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Chemist&Druggist
The Newsweekly for Pharmacy

C&D

10 January 2004

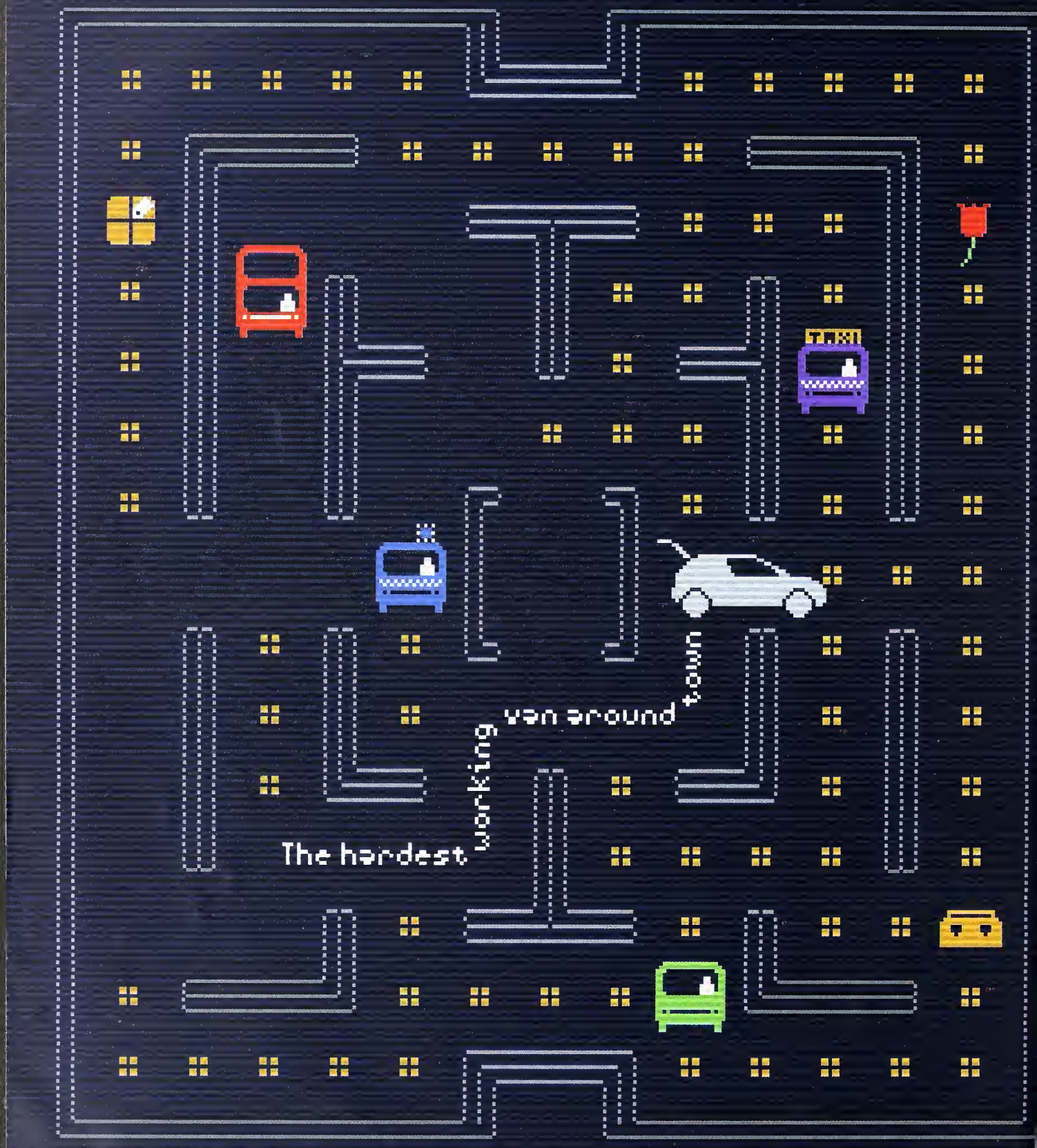
Violent attack on pharmacist tests data law

Supplementary prescribing of 'specials' likely

Boots toughs it out as Tesco cuts prices

Errors, audit trails and the RPSGB

100 years of Ford



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C&D

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Battered pharmacist is told he broke law

by Adrienne de Mont
ademont@cmpinformation.com

An Essex pharmacist knocked unconscious during a robbery has been accused of breaking data protection rules for identifying his attacker from patient medication records.

Brian Conn, manager at the Barry Shooter pharmacy in Chadwell Heath High Road, recognised his assailant and was able to retrieve his name and address from the pharmacy's PMRs. Mr Conn also managed to take a photo with a disposable camera seconds before the attack.

"I phoned the police expecting them to be grateful for the name and address which, together with the pictures, would be enough for them to arrest the youth. But they made me feel I had done something wrong, even though it was a totally unprovoked attack and I was trying to help the police," he said.

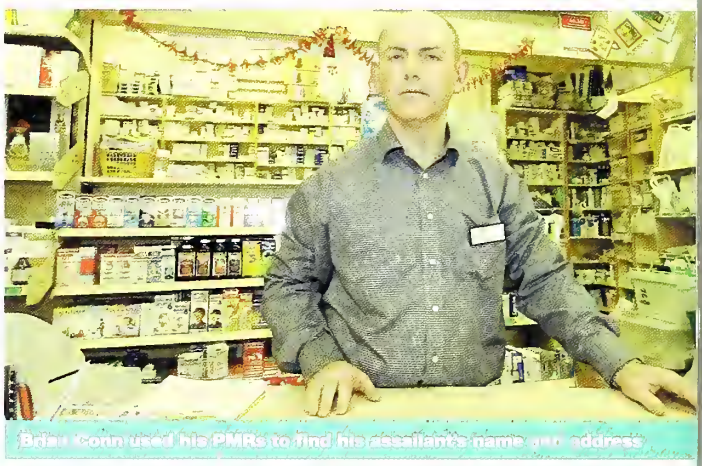
He later discovered that the person he spoke to was not a police officer, and the police have since told him they were grateful for the information.

Another concern was that the police failed to react to his panic alarm because there had been five previous false alarms at night when the shop was closed.

Mr Conn urges other pharmacists to contact their alarm company if they have had no responses to alarm calls.

Mr Conn is surprised at the amount of publicity his case has attracted, which has ranged from national newspaper articles to requests to appear on television.

NPA legal executive, Glyn Walduck, said: "It appears at first sight that Mr Conn was not acting unlawfully. There's provision in both the Data Protection Act and the Royal Pharmaceutical Society's Code of Ethics to disclose information where a serious crime has been committed. This could extend to the name and address of an attacker, but not necessarily the medicines he was taking.



Atlantic Syndication

Brian Conn used his PMRs to find his assailant's name and address

"Common sense has to prevail," he continued. "While patient confidentiality is paramount, exceptions can be made in certain circumstances."

The Royal Pharmaceutical Society pointed out that a section on confidentiality in the *Medicines, Ethics and Practice Guide* listed the occasions when information could be disclosed without the patient's consent. These include "to a police officer... who provides in writing confirmation that disclosure is necessary to assist in the prevention, detection or prosecution of serious crime."

No arrest of the assailant had been made as *C&D* went to press.

Update news

Signing up for Pharmacy Update in 2004 will provide you with over 30 hours of continuing education ... and if you are a new registrant it could cost you nothing.

Genus Pharmaceuticals, the company that sponsors the Update MCQ paper each month, will be refunding the registration fee for 50 lucky newcomers.

All new applicants (not registered for Update in 2002 or 2003) who sign up by the end of January will be entered in a draw for a refund.

There are two other good reasons to sign up before the end of the month:

- £5 discount off the 2004 registration fee
- entry into Update Knockout 2004, with £3,000 to be won.

For more information:
www.dotpharmacy.com
E-mail: mprebble@cmpinformation.com
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TRAINING

Drug theft prompts security update

by Asha Fowells
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Pharmacies in Jersey are now legally bound to have monitored burglar alarms and install them at their own expense.

In addition, all Controlled Drugs must be stored in safes, while benzodiazepines and dihydrocodeine medicines are to be kept in CD cabinets.

This follows a spate of pharmacy break-ins in December 2002, which sources at the States of Jersey suggested might have been related to a shortage of street drugs at the time. Pharmacist and proprietor Rob Reid said: "Clearly pharmacies were vulnerable, but I have had to find over £7,000 to install the extra security measures at my three shops."

Jersey's chief pharmacist Paul McCabe said: "There is no money allocated for this. It is up to pharmacists to incorporate any extra costs when they negotiate payment for the services they provide."

Chemist contractors' committee member Gwynn Jones said: "The ongoing monitoring costs will have to be incorporated in an increased dispensing fee and we hope this will be dealt with sympathetically when we come to negotiate later in the year."

PRESCRIBING

Sheffield PCTs pay drug costs

Sheffield PCTs have agreed to compensate pharmacists for any loss incurred as a result of a prescribing initiative.

Last month the four PCTs in Sheffield agreed to stop prescribing methotrexate 10mg tablets following a 'near-miss' incident. But LPC secretary Martin Bennett had warned that "it is important that contractors are not left picking up the bill for this safety measure".

The LPC had advised contractors to quarantine stock and seek compensation from their PCT. However, Sheffield South West prescribing advisor Liz Miller confirmed that all four PCTs covering the Sheffield area would make the ex-gratia payments through the LPC.

Wendy Harris, pharmacist at the National Patient Safety Agency, said: "Patients prescribed high doses find large quantities of 2.5mg tablets unacceptable."

Optipen warning

The MHRA has issued a warning following reports of patients having difficulty in using Aventis's Optipen Pro insulin pen injection system.

The company has received over 1,000 technical complaints, which in some cases have resulted in serious clinical events such as diabetic ketoacidosis, says the MHRA. Reported problems include plunger jams and/or inoperable pens; dose setting and injection difficulties; and confusion about dose delivered.

Health professionals should report problems to the MHRA. Replacement pens are available from Aventis Pharma.

For more information:

Aventis Pharma
Tel: 01732 584493.

More walking in

Health minister John Hutton has announced 11 more NHS Walk-In Centres will be opened in England, over the next two years.

The centres will open in Barking and Dagenham, Brighton, Darlington, Colchester, Gateshead, Huntingdon, Lewisham, Prestwich, Salford, Skelmersdale and Sunderland, and will bring the total up to 42.

MEDICINES

MHRA consults on unlicensed drugs use by supplementary prescribers

by Gary Paragpuri
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Pharmacists could be allowed to prescribe unlicensed medicines under the latest government proposals for supplementary prescribing.

In addition to unlicensed medicines manufactured in the UK (known as 'specials'), the Medicines and Healthcare products Regulatory Agency and the Department of Health have jointly proposed that supplementary prescribers be permitted to prescribe imported unlicensed drugs, and unlicensed medicines prepared by pharmacists from active pharmaceutical ingredients and inactive excipients.

Welcoming the proposals, NPA information services head Michelle Styles suggested there should not be a need to limit which medicines could be prescribed as part of supplementary prescribing because the clinical management plan – which both the independent and supplementary prescriber have to agree to – stated which drugs could be prescribed and thus acted as a safety net. In addition, supplementary prescribers would be working within their competency limits, she said.

RPSGB practice and quality improvement director David Pruce said the proposals closed a loophole preventing supplementary prescribers from doing their job. He highlighted the preparation of TPN products, which although formulated by specialist pharmacists, still had to be signed off by doctors.

Ministers have already accepted a recommendation by the Committee on Safety of Medicines that supplementary prescribers can prescribe licensed products 'off-label' and, according to the MHRA, the latest proposals seek to meet the government's objectives of improving timely access to treatment and medicines, and are an improved use of pharmacists' and nurses' skills.

Subject to consultation, the MHRA expects this change to be implemented by mid-2004.

Comments on the proposal should be sent to Roy Drepaul, MHRA, 16-139, Market Towers, 1 Nine Elms Lane, London SW8 5NQ (or e-mailed to *roy.drepaul@mhra.gsi.gov.uk*) to arrive by March 31.

According to the MHRA, if supplementary prescribers are excluded from prescribing unlicensed or extemporaneously products, it could impact on areas such as dermatology, paediatrics, and oncology. For example, if preparations such as dithranol or coal tar in yellow soft paraffin were excluded, it would severely restrict supplementary prescribing by pharmacists with an interest in dermatology.

Hospital paediatric pharmacists, who regularly advised on the use of unlicensed medicines such as spironolactone or clobazam suspension, would find supplementary prescribing impractical, as would oncology pharmacists if they wished to prescribe 'specials' such as lemon mucilage for sore throats, says the MHRA.

For more information:

www.mhra.gov.uk

Sheffield quit service funds pharmacy scheme

Sheffield pharmacists are being funded to run a smoking cessation scheme led by pharmacy support staff.

Twenty one pharmacies have enrolled in the scheme that began on January 1 and is being funded by the Sheffield Stop Smoking Service.

As part of the scheme, 33 pharmacy assistants have been trained to provide client counselling, carbon monoxide monitoring and up to eight weeks' NRT in instalments once their supervising pharmacist has requested a prescription from the patient's GP.

Pharmacies receive £12 for the initial session, £3.25 for the next four sessions and £2.50 for the final two sessions. An additional £1 fee is paid every time NRT is dispensed.

Susie Coates, of the Sheffield community pharmacy development unit which is co-ordinating the scheme, said: "We think that pharmacy will be able to contribute significantly towards the city's quit target. Hopefully when the scheme is assessed at the end of March, it will become long-term."

It is hoped the pharmacy scheme will help the city achieve its target for quitters which it is currently failing to do.

In addition, pharmacists are now able to directly refer patients onto the Sheffield Stop Smoking Service, and will receive £6 for every patient who succeeds in meeting the four-week quit target.

GPs warned 'not to get territorial with pharmacists'

by Fiona Salvage
fsalvage@cmpinformation.com

Doctors should "not get territorial" over pharmacist-led medication review schemes, a GP has warned.

Pharmacists added value to repeat prescribing schemes and cut GPs' workloads, West Northumberland PCT's clinical governance lead Bill Cunningham has said.

He highlighted a scheme in his area where pharmacists recommended 1,922 medication changes, 84 per cent of which were accepted by patients' GPs.

Dr Cunningham said that 47 per cent of the recommendations were clinical changes – of which 13 per cent were changes because there was no clinical evidence for the patient to be taking the medication; 8 per cent of the pharmacists' suggestions were linked to monitoring; and 45 per cent were computer system changes, where the database was inaccurate – 19 per cent of these included items that were no longer used or needed.

Three pharmacists saw medical records from 12 practices for 339 patients, taking 10 or more medications.

Pharmacists recommending medication review saves GPs' time

Questiontime

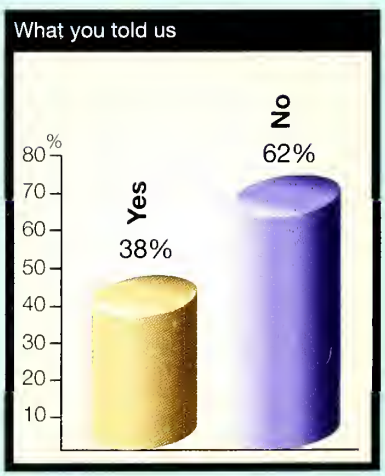
Sponsored by UniChem

Last week we asked you: "Do you think the North East London LPC is right to withhold money from PSNC?" You replied (see right):

This week's question: With drug-related crime rising, do you think it is reasonable for the government to pay for all community pharmacies to have instant video link ups with police stations?

- Yes
- No

You can record your vote on our website: *www.dotpharmacy.com*. You have until noon on January 13 to cast your vote. We will publish the results in *C&D*, January 17.



PRACTICE

Liverpool LPC tackles fraud

Liverpool LPC has drawn up a checklist to help pharmacists tackle prescription fraud.

The 'schedule of doubt' outlines factors that may indicate that a prescription is a forgery and describes typical signs of attempted prescription fraud.

The protocol has been prompted by various incidents reported by contractors to LPC secretary Jeremy Clitherow, including locum GPs presenting FP10s for large quantities of expensive inhalers without the knowledge of the surgery and prescriptions for CDs being presented at weekends containing spelling mistakes and legal irregularities.

LPCs can get copies of the schedule by contacting Mr Clitherow at *j.clitherow@btconnect.com*.

SURVEY

Side effects lead to non-compliance

Side effects are the main reason cited by patients for choosing not to take a medicine, American researchers claim.

One fifth of patients say that side effects were the main reason for non-compliance. The remaining patients claimed their medications were too expensive (17 per cent); they didn't perceive the need for a drug (14 per cent); and some found it difficult to get to the pharmacy (10 per cent). Of those surveyed, only 24 per cent claimed forgetfulness as the reason for not complying with the medication regimen.

CORRECTION

OTC author

Dr Shirley Bond is medical advisor to the Natural Menopause Advice Service and not the Women's Nutritional Advisory Service as stated in the November 22 issue of *Over The Counter*. The Women's Nutritional Advisory Service was founded by Maryon Stewart.

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Doctors concerned over costs of supervised methadone

by Adrienne de Mont
ademont@cmpinformation.com

Dundee GPs have expressed concern at the costs involved in a health authority plan to switch drug addicts to daily-supervised methadone consumption.

Dundee Local Healthcare Co-operative chairman and GP Dr Charles Carney has reportedly said that supervised consumption would give better control of addicts' behaviour and help to prevent leakage of methadone into the community but he claimed health chiefs had no idea how many addicts were receiving methadone and what the true cost of daily dispensing might be.

GPs are concerned about the potential costs of paying pharmacists £2.10 for dispensing CD prescriptions, plus £1 for each supervised consumption. Some 52 of the 69 pharmacies which dispense methadone in Tayside are providing the supervised service. The switch could put pressure on other health budgets struggling to cope with demand.

A Tayside Health Board spokesman confirmed that the financial implications were not yet known, but the aim was to improve control of methadone dispensing.

"We are currently developing a protocol for GPs which will improve the quality of prescribing and dispensing, and will mean we have better monitoring systems in place," she told *C&D*.

RPSGB rolls out new-look staff structure

The Royal Pharmaceutical Society has announced further details of how its staff structure will look as part of its plans to have seven staff directorates.

The directorates of Education and Registration; Fitness to Practice and Legal Affairs; Practice and Quality Improvement; and Corporate Strategic Development have been re-organised. While the Finance and Resource; and Public Affairs and Communication directorates have not changed, Council is due to consider the Publications directorate's future.

There are 10 vacancies among the 49 direct reports to the directors, mainly in the directorates crucial to the Society's role as a 'modern regulator': five of the six direct reports in the Fitness to Practice and Legal Affairs Directorate have yet to be appointed, as have two of four heads of department in the Practice and Quality Improvement directorate.

Recommendations for staff structures of the Scottish and Welsh executives will be brought forward after a review of their role and remit in the light of developing devolution, says the Society.

Kay Eddy (right) accepts the National Co-operative Chemists' first "Fit for the Future" award from chief operating officer for the specialist [illegible] Rankin. The pharmacist manager won the award for organising a diabetes awareness day at the NCC [illegible] Ravensthorpe, West Yorkshire, which pinpointed 11 previously undiagnosed patients. The award scheme has been developed to recognise pharmacists who develop patient focused services

Failure to stick to drug protocol put patients at risk

Two pharmacists gave schizophrenic patients a drug with potentially fatal side effects without checking it was safe to do so, the Statutory Committee heard.

Lambeth Hospital Pharmacy's principal pharmacist Neil Graham Spencer, together with pharmacist Danica Pejovic, gave 27 schizophrenic patients the anti-psychotic drug, clozapine, the supply of which is strictly controlled due to its side effects.

Geoffrey Hudson, for the Society, said: "Because of its side effects it is licensed for use only in circumstances where the prescriber, the patient and the pharmacists are registered with the Clorazil Patient Monitoring Service (CPMS)."

A major side effect of the drug is "the decrease in a number of certain white blood cells – a condition that can be a potentially fatal side effect." This meant that any patient requiring the drug had to have a blood test before it could be dispensed.

Mr Hudson said that although Mr Spencer and Mrs Pejovic were both familiar with and aware of the requirements surrounding the supply of the drug, they were in breach of the strict guidelines when approximately 27 patients were given clozapine between May and August 2001.

Mr Hudson said the situation was compounded by the fact that other staff members at the pharmacy brought the matter to Mr Spencer's attention.

"The Society says there should have been no supplies outside the scope of the CPMS, no matter how inconvenient that may have been [to patients]."

Mr Spencer was dismissed from his post in January 2002 and later unsuccessfully appealed against the decision.

Committee chairman Lord Fraser of Carmyllie QC said last month that, after looking at the evidence of computer entries, they could not allow the case to proceed against Mrs Pejovic.

The Committee considered the case against Mr Spencer for his failure to have proper systems for dispensing clozapine strictly in accordance with the requirements.

Mr Spencer said that what were termed breaches by the Society had occurred over a period of time when a small number of staff were dispensing the drug to patients who were in-patients or were living in supported housing, and had been taking the drug for quite a long time.

He said he had looked at a system of protocols or guidelines but had never quite completed it.

Mr Spencer said that patients who did not receive their medication could relapse into schizophrenia quite quickly. They could also suffer symptoms that could get worse if their supply of the drug was delayed.

Lord Fraser said Mr Spencer's admission of not having a proper system for dispensing the drug was sufficient to conclude that there was a failure on his part. This constituted misconduct but bearing in mind the comments made by his barrister and his own evidence, the committee issued a reprimand.

INDUSTRY

Bayer wins European court battle over Adalat

by Sasa Janković
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The European Court of Justice has ruled in favour of Bayer in a parallel imports dispute over its cardiovascular drug Adalat and annulled an earlier fine.

In October 2000 the Court of First Instance annulled the European Commission's 1996 decision that Bayer tried to limit deliveries to prevent parallel trade, as well as its accompanying £2.1 million fine, judging the Commission had not proven the existence of an agreement within the meaning of Article 81 between Bayer and its wholesalers.

This latest judgement upheld that of the EU's Court of First Instance and rejected the appeal made by the European Commission and the Bundesverband der Arzneimittel-Importeure - supported by the Swedish government and the EAEPC.

Edwin Kohl, president of the European Association of Euro-Pharmaceutical Companies, said: "While disappointing, this decision is a very narrow one that does leave the door open for the European Commission to take decisive action against other supply quota systems, and we encourage it to do this. Such systems are a direct attack against parallel trade and the proven benefits this brings to healthcare systems and consumers, as well as a challenge to the integrity of the EU Single Market."

However, the ruling was welcomed by the ABPI. Director-general Trevor Jones said: "This ruling is very encouraging for an industry that has especially suffered from the problems arising from parallel trade.

"I believe this will establish a positive way forward for innovative medicines, both now and in the future, so that we can achieve a more rational trade environment in Europe."

According to the ABPI, latest figures show that parallel trade costs the pharmaceutical industry some £1.4 billion a year, and that more than one in eight prescriptions in the UK are filled with a parallel-imported product.

There are believed to be as many as 40 other complaints pending with the European Commission against other manufacturers' supply quota systems.

For more information:
www.abpi.org.uk
www.eaepc.org

INDUSTRY

Neolab to distribute Apotex paroxetine in UK

Neolab is distributing Apotex's generic paroxetine in the UK following a High Court judgement in December that the product did not infringe GlaxoSmithKline's patent.

GSK markets its product under the brand name Paxil in the USA and as Seroxat in the UK.

Apotex launched its paroxetine hydrochloride tablets in the USA in September after becoming the first drug manufacturer to challenge the validity of patents there.

Apotex chief executive Dr Barry Sherman said at the time: "We consider it outrageous that GSK has kept an affordable alternative from consumers for years by asserting patents that they knew, or ought to have known, were either invalid or that our product did not infringe."

However, GSK still has the right to appeal against the UK High Court's ruling.

For more information:
www.apotex.com

NHS

Health access on NHS TV

The NHS has awarded the contract to provide its new digital TV service from this summer to MMTV Limited.

NHS Direct Digital TV will enable users to access health information from home, with £15 million invested in developing and running the service over the next three years.

Information will be provided on NHS services; illnesses and conditions; tests, treatments and operations; self-care; healthy living and current health issues.

Minister of state for health Rosie Winterton said: "The NHS Direct telephone service and website have already proved very popular with users. NHS Direct Digital TV will provide people with further choice in the way they can access health information from the NHS."

For more information:
www.doh.gov.uk

SkyePharma cuts jobs as revenues fall

by Sasa Janković
sjankovic@cmpinformation.com

SkyePharma is to cut 10 per cent of its workforce in research and development after issuing a profit warning for 2003.

In a statement, the company blames this on delays in concluding a number of key deals in 2003. It says this will lead to revenues for the year being substantially below the £85-100 million range predicted in its September interim results and below the £70m achieved in 2002.

Chief executive Michael Ashton said: "We are disappointed that we have not been able to meet the ambitious target we set ourselves in April of revenue growth in excess of 40 per cent. On the positive side, royalty income should more than triple for the full year after increasing fourfold in 2002."

However, he warned: "I can also report that the company has been in discussion with our partner GlaxoSmithKline over the royalty rate we receive on sales of Paxil CR. Legal advice received by SkyePharma leads us to believe that we are entitled to a substantial increase in the royalty rate from the date of entry of generic paroxetine in the US market. If we are unable to reach agreement on this issue, there is an arbitration procedure in place."

One Care Record Service contract remains

Two of the final three contracts to deliver the NHS Care Records Service in England have now been finalised.

CSC has been awarded the £973 million contract for the North West and West Midlands region and Accenture has won the Eastern region contract, worth £934 million. One remaining contract for the Southern region is still to be awarded.

Nicorette Range Abbreviated Prescribing Information. Presentation: *Gums:* Nicorette 4mg gum and Nicorette 2mg gum contain 4mg and 2mg of nicotine respectively in a chewing gum base. Original, Citrus or Mint flavour. *Patches:* Transdermal delivery system available in sizes (30, 20 and 10cm^2) releasing 15mg, 10mg and 5mg of nicotine respectively over 16 hours. *Inhalator:* Inhalation cartridge containing 10mg nicotine for oromucosal use via a mouthpiece. *Microtab:* Nicotine β-cyclodextrin complex 17.4mg, equivalent to 2mg nicotine. *Nasal Spray:* A metered spray bottle containing 10ml of 1.0mg/ml solution of nicotine for intranasal use. Each 50 microlitre spray delivers 0.5mg nicotine. **Indications:** *Patches & Inhalator:* Nicotine dependence and symptom relief in smoking cessation. *Gums & Microtab:* Intended to help smokers who want to give up smoking but who experience difficulty in doing so owing to their dependence on nicotine. *Nasal Spray:* Rapid relief of nicotine withdrawal symptoms in the treatment of nicotine dependant persons. **Dosage & Administration:** *Gum:* Each piece should be chewed slowly for 30 minutes. After 3 months ad libitum dosage, Nicorette gum should be gradually withdrawn. Maximum recommended daily dose: Nicorette 4mg gum: 15 x 4mg pieces. Nicorette 2mg gum: 15 x 2mg pieces. Not to be used by people under age 18 unless recommended by a doctor. *Patches:* Nicorette patches should not be used concurrently with other nicotine products and patients must stop smoking completely when starting the treatment. The recommended treatment programme should occupy 3 months. One Nicorette patch should be applied to a dry, non-hairy area of the skin on the hip, upper arm or chest in the morning and removed at bedtime. Application should be limited to 16 hours within any 24-hou Patients are recommended to commence with one 15mg patch daily for the first 8 weeks. Patients who have r abstinent should then be supported through a weaning period, consisting of one 10mg patch daily for 2 weeks by one 5mg patch daily for a further two weeks. Patients should be reviewed at 3 months and if abstinence has achieved, further courses of treatment may be recommended if it is considered that the patient would benefit. N used by people under age 18 unless recommended by a doctor. *Inhalator:* Adults & elderly – 6-12 cartridges/d weeks. Half no. of cartridges in weeks 9 & 10. Stop usage in weeks 11 & 12. Not to be used by people under *Microtab:* Adults & Elderly – The tablet is used sub-lingually with a recommended dose of one tablet per hou heavy smokers (more than 20 cigarettes per day), two tablets per hour. Most smokers require 8-12 or 16-24 ta day, not to exceed 40 tablets. Duration of treatment is individual but between 3 & 6 months is recommend nicotine dose should be gradually reduced by decreasing the total number of tablets used per day. Treatment s stopped when daily consumption is down to one or two tablets. Not to be used by people under age 18. *Nas* Adults: Use should be restricted to three months. The three month course consists of 8 weeks – as requi maximum of one spray in each nostril twice an hour for 16 hours per day. Following 2 weeks – reduce by hal weeks – reduce usage to zero. Children: Not for use by any person under the age of 18. **Precautions:** Peptic ulce

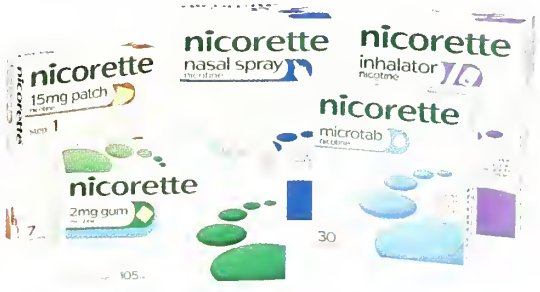
Number one and still going strong.

With a 52.4% share in the OTC market, it's no wonder Nicorette is the number one selling Nicotine Replacement Therapy brand.[1]

As inventors of the category, Nicorette offer the products, support and customer promotions responsible for driving growth in the stop smoking market over the last decade. What's more Nicorette has helped more smokers beat cigarettes than any other NRT brand.[1]

So to see your sales go from strength to strength, make sure you have the complete range to suit every smoker in stock today.

Please visit **www.comedis.com** to place an order or search for more information.



nicorette®
nicotine

The No. 1 Stop Smoking Brand

recent myocardial infarction, serious cardiac arrhythmias, systemic hypertension. Also *Patches, Inhalator, Microtab Spray:* Peripheral vascular disease, diabetes mellitus, hyperthyroidism, phaeochromocytoma. *Gum & Inhalator: Microtab & Inhalator:* Hepatic or renal disease. *Patches:* Recent cerebrovascular accident, chronic generalised logical disorders. *Microtab:* Gastric Disease. *Nasal Spray:* Chronic nasal disorders. **Contra-indications:** y & Lactation. *Gums, Patches, Microtab:* If the patient cannot give up smoking without NRT then a risk benefit int should be made. *Inhalator, Nasal Spray:* Do not use. Also. *Patch:* Non-smokers, known hypersensitivity to or component of patch. *Inhalator:* Non tobacco users, intolerance to nicotine or menthol. *Nasal spray:* Non users and those known to be allergic to the components of the spray. Persons up to 18 years of age. **Special s:** Rarely dependance. *Patches:* Erythema may occur. If severe or persistent discontinue treatment. *Inhalator:* oking before use. Best used at room temperature. *Nasal Spray:* Patients should stop smoking completely before therapy. Should not be used whilst the user is driving or operating machinery. **Adverse Effects:** *Gums:* al hiccups, indigestion, hyper-salivation, throat irritation, allergy, mouth ulcers. *Patches:* Application site reactions hema and itching), headache, nausea, dizziness, palpitations, dyspepsia and myalgia. *Inhalator:* Most commonly ritation of nose, throat and mouth, gastro-intestinal symptoms. *Microtab:* Most commonly heartburn, mouth hiccups, nausea, dizziness, unpleasant taste, headache, sensation of lump in throat. *Nasal Spray:* Principal adverse effects these occur commonly at the start of therapy but usually decline thereafter. Local: Nasal irritation (sneezing, runny nose), watering eyes and throat irritation. Systemic: headache and dizziness. Other: Sore nose, ear sensations, increased urination, tingling or burning sensation in the head, nose bleed, dyspepsia. **Pharmaceutical Precautions**: *Inhalator, Patches & Microtab:* Store below 30°C. *Gum:* Do not store above 25°C. **Legal Category**: *Nicorette 2mg gum, Nicorette 4mg gum, Nicorette Patches:* GSL. *Inhalator, Microtab & Nicorette Nasal Spray:* P. **Package Quantities & Cost (all trade prices correct at time of printing):** *Gum:* boxes of 15 pieces, 30 pieces and 105 pieces, in blister strips of 15 pieces. Nicorette 4mg gum (PL00032/0249, PL00032/0251, PL00032/0295), (£2.11) (15), (£3.99) (30), (£10.83) (105). Nicorette 2mg gum (PL00032/0248, PL00032/0250, PL00032/0283), (£1.71) (15), (£3.25) (30), (£8.89) (105). *Patches:* Cartons containing Nicorette patches in single sachets in the following quantities: Nicorette Patch 15mg (PL00032/0294) – packs of 7 (£9.07). Nicorette Patch 10mg (PL00032/0293) – packs of 7 (£9.07). Nicorette Patch 5mg (PL00032/0292) – packs of 7 (£9.07). Full prescribing information available on request. *Inhalator:* 6-Starter pack – (£3.39), 42-Refill pack – (£11.37) (PL00032/0163). *Microtab:* 30-Starter pack – (£3.57), 105s Pack – (£9.84) (PL00032/0239). *Nasal Spray:* Metered Spray Bottle, 10ml in packs of one (£10.99) (PL00032/0255). **PL Holders:** Pharmacia Limited, Davy Avenue, Milton Keynes, MK5 8PH, UK. Tel: 01908 661101. **Date of preparation:** September 2002. **Reference:** 1. IRI Data, 12 week to week ending 1st November 2003.

Tesco challenges Boots with price cuts

by Sasa Jankovic
sjankovic@cmpinformation.com

Tesco has mounted a challenge to the high street with price cuts worth £70 million, mainly on its babycare and health and beauty lines.

Prices will fall by an average of eight per cent on over 600 products.

Tesco director Tim Mason said: "We've invested over £1.3 billion in cutting prices over the last six years and now we are continuing to get even cheaper for customers by cutting the price of their shopping in 2004."

In a statement, Tesco said: "Parents shopping for a typical basket of 12 baby products can save a staggering 11 per cent when shopping at Tesco compared to Boots."

Boots spokesman Matthew Dransfield said: "Boots carries 50,000 products at any one time, many of which are exclusive to us, and we have been reducing prices on our basic product lines since last year. This announcement from Tesco is testament to our success."

INDUSTRY

Shire moves to block rival

Shire Pharmaceuticals Group subsidiary Shire Laboratories has filed a patent infringement lawsuit in the USA against Impax Laboratories to block a rival hyperactivity drug launch.

The lawsuit results from an Abbreviated New Drug Application filed by Impax for a generic version of 30mg Adderall XR, which Impax is seeking to market before the expiration of patents in 2018.

Adderall XR is Shire's leading extended release attention deficit hyperactivity disorder medicine.

Information and support service

The Prescription Only Medicine sector of Pfizer Pharmaceuticals is the first POM manufacturer to sign up to CoMedis.com to provide its customers with online information.

Peter Skinner, business director for CoMedis.com, said: "CoMedis.com will not be seeking to develop a script-offering platform. However, providing information on prescription medicines via CoMedis.com is an excellent additional service we are pleased to offer to users."

Pharmacists will still need to contact Pfizer's medical information team on 01304 616161 for more complex product information.

INDUSTRY

ABPI welcomes NHS expenditure growth

The ABPI has hailed figures from the Office of National Statistics showing a five year growth in NHS expenditure as making a major contribution to the health of the nation.

The figures show spending on public healthcare in the UK has risen from nearly £45 billion in 1997 to more than £67bn in 2002, a 45 per cent rise over five years. At the same time, expenditure on branded prescription medicines has remained constant at about 12 per cent of NHS expenditure.

"Increased spending on health by the Government is very welcome," said Dr Trevor Jones, director-general of the ABPI.

"Yet while more money has been invested in innovative medicines, this has grown in line with the rest of NHS expenditure.

"It has been recognised for some time that NHS patients have not benefited from modern developments in medicines to the same extent as people in other countries. These figures show that this disadvantage is gradually being overcome.

"It is also important to remember that the increased expenditure on medicines is almost solely driven by a greater level of prescribing, mainly thanks to various Government initiatives that are reducing death rates from heart disease, cancer and other diseases."

For more information:

www.abpi.org.uk
www.statistics.gov.uk

GSK loses Augmentin dispute

The US Court of Appeal has ruled in favour of Geneva Pharmaceuticals, Teva Pharmaceuticals and Ranbaxy, and upheld rulings that invalidated GSK's US patents for its antibiotic Augmentin.

GSK says it continues to be committed to its newer Augmentin antibiotic medicines, Augmentin ES and XR, which now represent nearly 35 per cent of the total number of prescriptions being written for branded and generic Augmentin.

How well managed are you?

UK businesses can prove they are well managed by entering a new business award from The Institute of Directors and Cranfield School of Management.

All entrants will receive a benchmarking report comparing them with others in their sector. Those short-listed will be invited to an award ceremony in London.

Application forms can be found at *www.som.cranfield.ac.uk/som/groups/opsman/iodsurvey/entry.asp* or from Dawn Gallyot at Cranfield School of Management on 01234 751122.

Subsidiary for Paradigm opens

UK drug discovery company Paradigm Therapeutics has set up a wholly owned Singapore subsidiary based in the Biopolis, a new facility for biomedical R&D in Asia.

Dr Ian Gray has been appointed head of research of Paradigm Therapeutics Singapore, joining from GlaxoSmithKline Pharmaceuticals, where he was manager of molecular genetics.

Barr gains rights

Barr Laboratories is to acquire the exclusive rights in the USA and Canada for Loestrin and Loestrin FE oral contraceptive products from Galen Holdings. The deal includes a settlement of pending litigation between Barr and Galen regarding Galen's femhrt hormone therapy and Estrostep oral contraceptive products that would allow Barr to launch generic versions six months before patent expiry.

GSK may owe $6bn

GlaxoSmithKline has received a claim from the US government for $2.7 billion (£1.5 billion) in additional taxes from 1989-96. Interest, which GSK estimates to be $2.5 billion, would also be payable, bringing the total owed to about $6.2 billion. GSK plans to contest the claim.

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Working together to plan core ranges for the pharmacy sector

Heinz

Comment from the Editor

It was a mixed blessing that the media picked up on the assault of a community pharmacist (*p4*). It was shocking that the pharmacist was knocked unconscious but gratifying that another assault on a healthcare professional did not go unnoticed. While the Government tries to tackle the ever growing menace of the public attacking workers on NHS property – be it in hospitals or the GP surgery – the spotlight was put on the other key NHS health professionals, who happen to operate from their own premises, the high street pharmacy. About time, too, as the Government's latest initiative for dealing with violence and intimidation in the NHS, launched just before Christmas, barely touches on what can be done to help the community pharmacy.

It is interesting, though, that the administration is recognising that pharmacies can attract 'undesirables' due to the drugs stocked, the cash takings and possibly the later opening hours pharmacies are expected to keep. Daylight raids on pharmacies (and post offices for that matter) by gun-wielding desperados are not uncommon.

In Jersey, the recognition that a spate of incidents was probably due to a shortage of illicit drugs in the underworld has prompted a new law to make it mandatory for pharmacies to have a monitored burglar alarm system. Despite it being a worthy idea, it is unfortunate that the cost has fallen to the contractors. Negotiations on the global sum may help contribute towards future monitoring costs.

It is unfortunate too, that when a direct line to the police station is installed, the police may be deterred from responding due to numerous false alarms, as was the case in Essex. What would benefit community pharmacy is some indication from the Government that the high street chemist is as much a part of the NHS as A&E or the GP surgery, and should benefit fully from any schemes for improved security.

Negotiations on the global sum may help contribute towards future monitoring costs

Yourviews

AAH Pharmaceuticals' group managing director and BAPW chairman Steve Dunn says...

... for IT's sake let's pool our knowledge

It is extraordinary that such a major initiative as the NHS national IT programme should be taking place without the involvement or input of organisations which have been, and remain, at the cutting edge of many key technological advances in the hospital and community pharmacy sector.

Those charged with awarding and overseeing the national contracts have consulted the private sector via Intellect UK's healthcare advisory committee, but this is a forum dominated by the voices of large IT companies such as BT and IBM. Little heed has been given to niche specialists which, although ineligible to tender for contracts, have a wealth of knowledge that could help deliver them.

It is precisely because of this that AAH and a number of other major pharmacy organisations have formed an additional advisory body, the BAPW Pharmacy Systems Group, to lobby and, hopefully, advise the Department of Health directly.

Steve Dunn: pharmacy ordering and management systems are key to patient care... the providers must be involved

The DoH itself has called for pharmacy to be integrated into the primary care health team so, logically, pharmacy IT providers should be involved in the development of key pharmacy IT systems. While true that major IT companies possess an extremely high level of expertise in their field, niche operators have been closely involved in healthcare IT and should be a part of the NHS IT programme.

Within the existing consultation process, the onus has been on tendering companies to seek out the advice of niche specialists themselves, rather than their being automatically involved. So far, this has not happened to any great degree.

But pharmacy ordering and management systems are key to patient care and the providers of these systems must be involved.

We have already heard concerns that the 550-page tender specification is too broad-based and only specifies, in general terms, the more non-technical requirements that contractors must meet.

It would be a tragedy if – as in the case of the London Ambulance Service's computer-aided dispatch system in 1993 – we end up with problems caused by a too precipitate approach to what is a highly complex and risk-oriented programme of modernisation.

I believe that only by utilising the specialist knowledge already existing within the healthcare sector will we see the delivery of the more efficient and effective health service promised in the *NHS plan*.

HOSPITAL REPORT

Pharmacists should be more visible

Every so often it is useful to look at hospital care from a different viewpoint. There are basically three different viewpoints on the triangle – healthcare professional, patient and relative/visitor. As a hospital pharmacist I don't often see the view from the patient's perspective, but I have recently experienced hospital as a visitor (luckily not as a patient).

From that perspective, it is easy to see why the public think the service is entirely run by doctors and nurses. There is no sign of pharmacists, physiotherapists, dieticians or anyone else. Even if they were to make an appearance, the majority of the public would assume them to be doctors, if wearing a lab coat, or nursing staff if wearing any other sort of uniform.

How on earth can you possibly overcome this and ensure that pharmacy is recognised as part of the hospital service? Hopefully, most patients should be aware

Unfortunately, the visibility of the pharmacist varies over the UK

that pharmacists exist to clarify their medication needs and counsel them on their medication.

Unfortunately, the visibility of the pharmacist varies over the UK. The resources are not there to staff pharmacy departments to the levels required to achieve this uniformly. Not only is there no money in the hospital budgets to increase staffing, but the number of pharmacists wanting to work in hospital is falling. The large student loan repayments sit more easily within the enhanced salaries of community pharmacies than the lower hospital salaries.

So how can we use pharmacists more effectively and get them out working with patients? A public awareness campaign would be helpful – perhaps extending the "ask your pharmacist" campaign to hospital wards?

Written by a senior hospital pharmacist

TOPICAL REFLECTIONS

The moment of truth approaches

The Government is soon to publish the details of its proposed relaxation of the control of entry regulations for community pharmacy contracts. The period of consultation is over and most submissions are now in the public domain.

I would have expected a divergence of opinion over the detail and consequence of the regulations but in this case there has been almost unanimous agreement that unless very strict, transparent guidelines are issued, chaos could ensue.

To most impartial observers the question that comes immediately to mind is, why the necessity for change? But this was outside the consultation's terms of reference. Instead we are left with the ridiculous situation of proposals that will be implemented contrary to the almost unanimous wishes of interested parties.

Whether the Government has listened sympathetically remains to be seen. I fear the final decision will sacrifice the structured future of community pharmaceutical services in favour of an ideological compromise. Political face may be saved but the chance to confirm community pharmacy as essential to the nation's health will have been lost.

Everyone needs OTC training

Sheila Kelly, PAGB director, is confident that the pace of change for switching POM medicines to P sale will increase (*C&D, January 3, p10*). She advocates a change of emphasis for pharmacist training from the current product-focused system to a programme accounting for the needs of the wider health agenda. She also wants our comments.

The wider health agenda includes GPs, nurses and their staff.

Training on the effective recommendation of OTC medicines should address the contribution required by all health staff and should not just be aimed at community pharmacies. With the help of the pharmaceutical industry, PCTs should help to arrange multi-disciplinary training sessions so all our roles are mutually understood.

We must then educate the public to consult more objectively the best professional for advice. Presently the National Pharmaceutical Association is funding another of its commendable 'Ask Your Pharmacist' campaigns. Perhaps the Department of Health and the pharmaceutical industry should now also invest in these campaigns and increase public awareness of the quality of that advice.

If OTC medicines are ever to become the integral part of an NHS medicines strategy that Ms Kelly desires then the industry has an essential role to play. It has the power to help in training professionals and to educate the general public about how to take responsibility for its own health.

Slim pickings or fat profits?

I am perhaps as guilty as any other pharmacist in exploiting the commercial potential of slimming aids. Certainly the obsession that the public has with its weight lends itself to many commercial opportunities but, as with many other products purchased from a pharmacy, they could be considered, by the consumer, as being professionally endorsed.

The latest craze is the low carbohydrate Atkins diet and demonstrating commendable opportunism, Boots has now launched a range of low carbohydrate slimming products specific to the needs of the Atkins customer (*C&D, January 3, p6*). But they are already on the defensive.

Even as the launch was announced they were trying to justify their decision.

The British Dietetic Association has repeated its concerns over the long-term use of the Atkins diet but these have been ignored by Boots. It will have been losing sales of conventional meal replacements and the Atkins products are designed to plug that gap. I am sure also that the range will carry a strong warning that they will only help if used in conjunction with a calorie controlled balanced diet.

The best dietary advice for the overweight is to consume fewer calories, eat a balanced diet and increase exercise. The Boots Atkins range cannot satisfy these criteria. They may make good commercial sense but I consider they are professionally unjustified.

Food Intolerance Week
January 26-31
Tel: 020 8303 8525

Bug Busting Day
January 31
Te: 020 7686 4321
www.nits.net/bugbusting

Raynaud's & Scleroderma Awareness Month
February
Tel: 01270 872776
www.raynauds.demon.co.uk

Eating Disorders Awareness Week
February 1-7
Tel: 01603 621414
www.edauk.com

Contraceptive Awareness Week
February 9-15
Tel: 020 7923 5201
www.fpa.org.uk

National Impotence Day
February 14
Tel: 0870 7743571
www.impotence.org.uk

No Smoking Day
March 10
Tel: 020 7916 8070
www.nosmokingday.org.uk

Daffodil Day (Marie Curie Cancer Care)
March 12
Tel: 020 7599 7777
www.mariecurie.org.uk

Brain Injury Awareness Week
March 15-21
Tel: 020 7841 0245
www.headway.org.uk

National Cystic Fibrosis Week
March 20-2[illegible]
Tel: 020 8464 7211
www.cftrust.org.uk

Prostate Cancer Awareness Week
March 22-28
Tel: 020 8222 7622
www.prostate-cancer.org.uk

National Bowel Cancer Awareness Month
April
Tel: 020 7381 9711
www.coloncancer.org.uk

PSP (Progressive Supranuclear Palsy) Magnolia Day
April 8
Tel: 01327 860299
www.pspeur.org

Mental Health Action Week
April 11-18
Tel: 020 7802 0313
www.mentalhealth.org.uk

National MS Week
April 18-25
Tel: 020 8438 0700
www.mssociety.org.uk

Parkinson's Awareness Week
April 18-25
Tel: 020 7931 8080
www.parkinsons.org.uk

National Depression Week
April 19-23
Tel: 020 7633 0557
www.depressionalliance.org.uk

Arthrogryposis Appeal & Awareness Week
April 21-27
www.tagonline.org.uk

Arthritis Care Week
April 25-30
Tel: 020 7380 6500
www.arthritiscare.org.uk

World Asthma Day
May 4
Tel: 020 7226 2260
www.asthma.org.uk

Psoriasis Awareness Week
May 15-22
Tel: 01604 711129

National Smile Week
May 16-22
Tel: 0870 770 4014
www.dentalhealth.org.uk

Epilepsy Week
May 16-22
Tel: 01494 601300
www.epilepsynse.org.uk

National Allergy Week
May 17-21
Tel: 020 8303 8525
www.allergyfoundation.com

Autism Awareness Week
May 17-24
Tel: 020 7903 3593
www.nas.org.uk

World No-Tobacco Day
May 31
Tel: 020 7630 1981
www.un.org

Everyman Male Cancer Awareness Month
June
Tel: 020 7970 6030
www.icr.ac.uk/everyman

National Osteoporosis Month
June
Tel: 01761 471771
www.nos.org.uk

Stillbirth and Neonatal Death Society Awareness Week (SANDS)
June 7-13
Tel: 020 7436 7940
www.uk-sands.org

British Heart Week
June 5-13
Tel: 020 7935 0185
www.bhf.org.uk

National Tampon Alert Week
June 7-12
Tel: 0161 748 3123
www.tamponalert.org.uk

National Diabetes Week
June 13-19
Tel: 020 7323 1531
www.diabetes.org.uk

For Relief of Glaucoma (FROG) National Awareness Week
June 7-13
Tel: 020 7737 3265
www.iga.org.uk

Sickle Cell Awareness Day
July 4
Tel: 020 8961 7795
www.sicklecellsociety.org

Alzheimer's Awareness Week
July 4-10
Tel: 020 7306 0606
www.alzheimers.org.uk

Sexual Health Week
August 2-8
Tel: 020 7923 5201
www.fpa.org.uk

British Cardiac Patients Association Awareness Day
September 8
Tel: 01954 202022
www.bcpa.co.uk

National Eczema Week
September 18-22
Tel: 0870 241 3604
www.eczema.org

Stroke Awareness Week
September 27 - October 1
Tel: 020 7566 0300
www.stroke.org.uk

Breast Cancer Awareness Month
October
Tel: 020 7384 2984
www.breastcancercare.org.uk

Lupus Awareness Month
October
Tel: 01708 731251

Europe Against Cancer Week
October
Tel: 020 7269 3043

Stroke Awareness Week
October 1-11
Tel: 020 7566 0319
www.stroke.org.uk

World Mental Health Day
October 10
Tel: 020 7633 0557
www.un.org

Scar Awareness Week
October
Tel: 01482 222200
www.scarinfo.org

Indoor Allergy Week
November 15-19
Tel: 020 8303 8525

World AIDS Day
December 1
Tel: 020 7814 6767
www.worldaidsday.org

Pharmacists should be alert for signs of phenytoin toxicity in cancer patients, advises *Mary Allen*

Use of phenytoin

THE COLLEGE OF PHARMACY PRACTICE

This course (module 1292), in association with multiple choice questions being published in C&D February 7, provides one hour's continuing education

- To know when phenytoin is used in palliative care
- To know when to challenge doses
- To understand why toxicity may occur
- To recognise symptoms of phenytoin toxicity
- To know what to do about it

Palliative care for cancer patients includes the use of a whole range of drugs. Analgesics and anti-emetics spring easily to mind, but cancer patients may be taking some medicines less readily associated with palliative care.

Community pharmacists can contribute to the safe and effective use of these drugs, particularly as patients increasingly remain living at home, receiving care through hospital clinics and their GPs, perhaps with support from specialist community-based palliative care nurses and doctors.

This article looks at phenytoin, an old drug indicated for all forms of epilepsy and also trigeminal neuralgia. It is now used less frequently as a mainstream anticonvulsant, largely because newer drugs have come along and because of long-term side effects such as gingival hyperplasia.

Phenytoin is used in palliative care in patients:

- with brain metastases who are having fits
- following brain surgery
- with neuropathic pain.

However, cancer patients receiving phenytoin are generally more ill and frail than people with epilepsy who are otherwise healthy. This, plus poor prescribing, can lead to adverse effects which can reduce quality of life in patients who are already often seriously ill. Some patients admitted to hospices with apparent symptoms of progressive disease have, in fact, been found to be suffering from phenytoin toxicity. Community pharmacists can help reduce the potential for this by:

- Challenging any doses (and dose increases) that seem inappropriate, and routinely checking doses (for example, those above 300–400mg) in frail patients to eliminate possible prescribing error.
- Checking with other health professionals (GPs, specialist nurses) that patients' plasma phenytoin levels are appropriately monitored.
- Alerting prescribers and nurses who look after palliative care patients in the community (specialist palliative care home care nurses and district nurses) to some important drug interactions that may affect treatment or even be dangerous.

What is a normal dose?

Initial doses in adults are usually 3–4mg/kg body weight with subsequent adjustment if necessary. This means, in practice, that:

- most 70kg (11 stone) adults would need around 200–300mg daily
- most 100kg (about 15.5 stone) adults should need around 300–400mg daily, although some patients may need a higher or lower dose
- a dose of 150–200mg daily should suffice for most 50kg (7.75 stone) adults.

The normal maintenance dose of phenytoin for otherwise healthy patients is in the range 200–500mg daily. This can usually be given as single dose at night or, in a minority of patients, divided doses twice (or three times) daily. If tolerated, a single dose can help improve compliance. In exceptional circumstances, a higher daily dose may be required, but this is unlikely in a cancer patient or anyone who may have hepatic (or renal) impairment.

Specialist palliative care home nurses and district nurses should be aware of phenytoin's interactions with other drugs

Phenytoin should be introduced in small doses with gradual increments until control is achieved or toxic effects are observed. Plasma level determinations are sometimes required for optimal dosage adjustments. The clinically effective plasma level is usually 10–20mg/litre (40–80micromoles/litre). As it takes seven to 10 days to achieve steady state plasma levels, and because phenytoin has a small therapeutic ratio, it is important that dose increases should be small and at intervals not shorter than seven to 10 days, to avoid toxicity.

Therapeutic ratio

Blood (plasma) levels of phenytoin are affected by several factors, which may be particularly significant in seriously ill patients. These include:

- limited capacity metabolism of phenytoin (even in healthy patients)
- plasma protein (mostly albumin) levels
- liver impairment
- other drugs.

Phenytoin is metabolised in the liver. For most drugs, the amount of drug metabolised in a given time is proportional to the amount present in the blood (hence the drug's half-life is the time for half the drug to be metabolised).

However, phenytoin differs in that it has only limited capacity metabolism – the enzyme system dealing with it is saturable, leaving

Continued on page 18 ▶

excess drug hanging around waiting to be metabolised, which increases plasma levels. So, a small increase in dose given can produce a BIG increase in blood level. This can happen in any patient, but can be particularly problematic in a patient with a 'dodgy liver'.

Plasma protein (albumin) binding

In the blood, phenytoin is 90 per cent bound to plasma proteins, mainly albumin. This means for every 10mg of phenytoin in plasma, 9mg is bound to albumin (therefore not active) and 1mg is free to be active in body tissues (in this case the brain). In healthy patients taking only phenytoin, this albumin binding doesn't matter because there is an equilibrium between that which is bound and that which is free – as some of the drug gets used up (metabolised) more is released from the bound form to restore the 90 per cent ratio.

Although the therapeutic range of phenytoin is quoted as 10-20mg/litre, this represents a 'real' therapeutic range of 1-2mg free drug, with the remaining 9-18mg/litre (that is 90 per cent) bound to albumin.

Problems can occur if patients are taking other drugs which bind to albumin and which may displace the phenytoin from its binding sites (one form of drug interaction), or – more importantly in practice – in a minority of patients who have less albumin to which phenytoin can bind. Both these can occur in cancer patients.

Fortunately, low albumin is rare except in seriously ill patients who are uraemic and losing albumin through the kidneys, or who have extensive metastatic liver disease or other hepatic impairment including cirrhosis. As cancer patients whose disease has spread may have liver metastases, this is obviously a potential problem if they take phenytoin.

Laboratory results for plasma phenytoin levels are commonly given as total plasma phenytoin, that is, all the phenytoin detected in the plasma whether or not it is protein-bound (free phenytoin plus albumin-bound phenytoin). For healthy patients with normal albumin this is fine because of the normal equilibrium between bound and free drug. But for people with low albumin the results can be dangerously misleading.

If someone has only half the normal levels of albumin, a seemingly normal phenytoin plasma result can be a dangerously toxic one; 20mg/litre may seem fine, but much more of this is free drug and will greatly exceed the normal 1-2mg/litre therapeutic range. So lab results need adjusting to account for this, and prescribers should remember (or be reminded) that, for these patients, the safe therapeutic range is much lower.

Some important reminders about phenytoin

Normal dose range 200-500mg daily	A healthy 70kg (11 stone) patient will usually need about 200-300mg
Narrow therapeutic margin: optimum response 10-20mg/litre	Needs plasma level monitoring at regular or appropriate intervals
90 per cent bound to plasma protein	This matters if patients have low albumin, as in advanced metastatic liver disease
LOTS of drug interactions	Can affect both phenytoin levels AND those of the interacting drug

Drug interactions

Drug interactions with phenytoin are numerous, and are indicated in the *Drug Interactions Appendix* in the *British National Formulary* and in the *Summary of Product Characteristics (SPC)* for Epanutin, available on *www.medicines.org.uk*. Phenytoin affects blood levels and activity of other drugs mainly through its effects as a hepatic enzyme inducer, reducing the blood levels of other drugs. Many drugs may affect phenytoin's plasma levels, which is important as it has a narrow safe therapeutic range. So the 'normal' phenytoin dose may be rendered ineffective or toxic if other drugs are introduced. Even other anticonvulsants can affect phenytoin levels, sometimes by displacement at binding sites as well as by affecting its metabolism.

In cancer patients with brain metastases one particularly significant drug interaction is that between phenytoin and dexamethasone, two drugs frequently used together to reduce the effects of cerebral tumours. The enzyme induction activity of phenytoin may markedly reduce blood levels of dexamethasone, necessitating a dose adjustment.

Phenytoin also interacts with warfarin, so careful monitoring of INR is required with possible adjustment of warfarin (or treatment review by the oncologist/palliative care specialist).

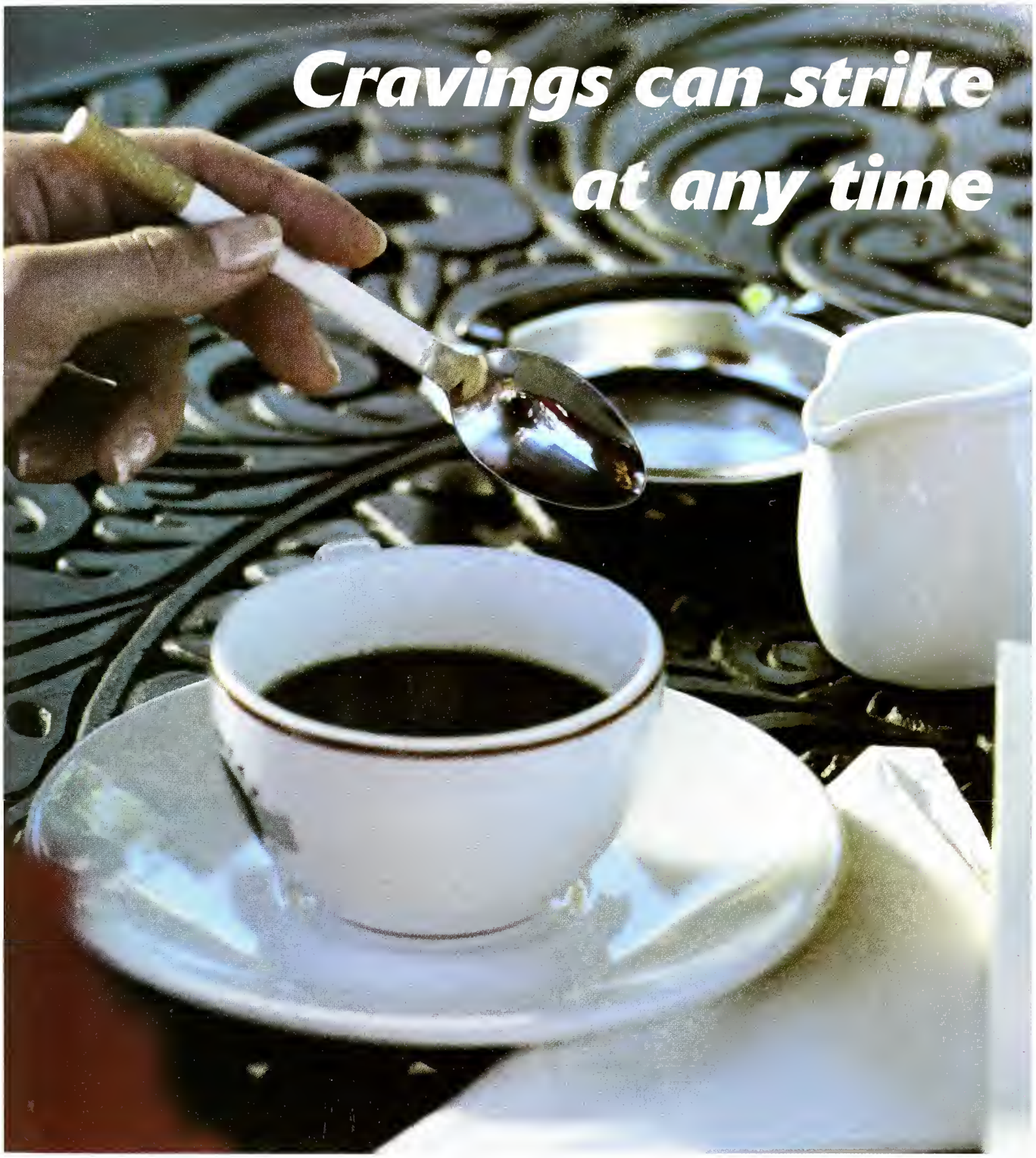
Side effects

The side effects of phenytoin are many and are listed in the above references (*BNF* and *SPC*). Very ill cancer patients don't usually have to worry about long-term effects like gingival hyperplasia, but may be vulnerable to inadvertent toxicity through hepatic impairment or drug interaction. All patients for whom phenytoin is prescribed (or their carers) should be made aware of the possibility of blood disorders like leucopenia and thrombocytopenia and the need to report any signs such as sore throats or bruising (*see BNF monograph*).

The signs of toxicity are usually nystagmus (rapid eye movements), which normally occurs at plasma levels above 20mg/litre, ataxia (above 30mg/l), and dysarthria (difficulty with pronunciation) and lethargy (above 40mg/l). However, sometimes there is no evidence of these signs even at levels as high as 50mg/litre. There are also reports of movement disorders: chorea, dystonia, or tremor.

Toxicity is probably best treated by missing a couple of doses then carrying on with a dose that relates to the patient's body weight and takes into account any other factors such as albumin levels and drug interactions. Some doctors (and carers) are reluctant to omit doses because abrupt withdrawal of phenytoin can precipitate seizures. While this is true for the patient with normal levels, it is not a problem when

Continued on page 20 ▶



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www.Click2Quit.com

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levels are toxically high! Careful plasma monitoring is required until normal levels are restored.

Points to emphasise

In conclusion, phenytoin can be a useful but tricky drug in cancer patients. Health professionals need to remember that, for this group of patients, who are usually very unwell and taking lots of other drugs:

- Appropriate plasma phenytoin monitoring is crucial, especially after dose increases, apparent disease progression or any newly observed symptoms or signs.
- Saturable metabolism means that small dose increases may cause large increases in blood (plasma) levels, so all dose increases should be in small increments and carefully monitored.
- Hepatic impairment may affect metabolism.
- Low albumin levels (rare but significant) can greatly increase toxicity.
- In low albumin, plasma levels below 10mg/litre may be therapeutic so apparently 'normal' levels may be toxic.
- Drug interactions are important and require adjustment of either the phenytoin or the interacting drug.
- Community pharmacists (and nurses) should routinely challenge:
- any doses above 400mg
- any dose increases in increments greater than 25-50mg
- any doses they feel unhappy about.

By being aware of the pitfalls, community pharmacists can help prevent phenytoin toxicity and ensure safe and effective use.

Case study: William

William, in his 50s, was admitted to a hospice following collapse and subsequent diagnosis of cerebral and lung metastases following treatment for malignant melanoma some years before. Three weeks before admission, William had a fit at home. His GP had subsequently taken a blood level showing 10mg/litre of phenytoin. Recognising this to be at the lower end of the therapeutic range the GP doubled his dose from 300mg to 600mg!

William was very poorly on hospice admission, with nystagmus and some twitching. A blood test showed levels of 25mg/litre. The hospice staff omitted a couple of phenytoin doses and increased his prescribed dexamethasone temporarily to compensate for the effects of the phenytoin on its activity.

Following a reduction in dose to 350mg phenytoin he improved vastly and became well enough for a precious trip out with his family before dying of his cancer.

If someone (pharmacist, community nurse?) had queried the large incremental dose increase, perhaps this could have been avoided.

Case study: John

John was a large 40-year-old admitted to a hospice on a dose of 700mg phenytoin daily, prescribed to control fits caused by cerebral metastases.

His drug regime on arrival was a nightmare cocktail of drug interactions (he was taking dexamethasone, warfarin and NSAIDs among other drugs).

His dose of phenytoin was considered to be too high. It was reduced to 600mg while awaiting a plasma phenytoin result, and John suffered an event that involved some twitching of one limb. The nursing staff on duty thought this was a fit, as did John's wife – she had previously been warned that abrupt withdrawal could precipitate fits and so felt very upset by the reduction.

His plasma phenytoin level (blood taken the same day as the dose reduction) was found to be 21.8 mg/litre – outside the normal therapeutic level, but not excessively so. However, blood tests showed that his plasma albumin levels had fallen to around half those of a healthy person, resulting in a corrected phenytoin level greater than 40 mg/litre.

Despite this, although very poorly, John was not exhibiting any of the usual symptoms of phenytoin toxicity (nystagmus, dysarthria etc). The team decided that his 'twitching' was probably due not to lack of seizure control, but rather to phenytoin toxicity which can produce choreas and dystonias. After a dose reduction to 400mg daily and careful monitoring, his plasma levels soon dropped to a level within the therapeutic range.

As well as causing toxic effects, John's high levels of phenytoin were rendering ineffective the normal doses of dexamethasone used in controlling the problems associated with cerebral and liver metastases, through increased metabolism of the latter drug via hepatic enzyme induction. The dose of dexamethasone was increased to compensate for this, to good effect.

John died fairly soon after this of his advanced disease, but as a result of his phenytoin dose reduction, he became more animated and regained some of his ability to think and talk, allowing him some precious talking time with his family.

Could a community pharmacist or nurse perhaps have prevented this situation by querying John's large dose with the prescriber?

Mary Allen, FRPharmS, is a part-time community pharmacist and hospice pharmacist in Herts.

Reducing phenytoin levels from toxic to normal therapeutic levels can improve patients' quality of life

Actionplan

1. Using your patient medication records, find out which of your clients are taking phenytoin. Now try to establish how many of these are receiving palliative care. Was phenytoin added to their drug regimen as a result of their new condition? Does the dosage fall within the suggested limits? If not, is there any reason?

2. Review the 'newer' drugs used to treat epilepsy (*BNF 4.8*). A new NICE report – *Epilepsy in Adults – Newer Drugs* (expected to be published in March 2004) – may suggest revised indications for some of the newer anti-epileptic drugs. Using this and your review, do you consider that phenytoin should be less frequently the drug of choice in palliative care? Should you discuss this with doctors starting phenytoin for such patients?

3. Revise the distribution of drugs in the body with particular reference to the frail and elderly.

4. Are there other drugs with a high potential for protein binding, for which the blood level analysis results might not reflect the clinical effect?

5. Many serum drug level tests should be performed some time after starting the drug. Think about why, and list some in your practice workbook.

Distance learning for pharmacists

Pharmacists using **Pharmacy Update** for continuing education are reminded of the need to test. With the support of Genus Pharmaceuticals, C&D's readers can self-test their progress by using the multiple choice questions [illegible] to be inserted in the February 7 issue, which will cover this week's CPP-accredited module, together with [illegible] January 3 and 31 issues. These will cover:

- **Obesity (1291)**
- **Phenytoin case study (1292)**
- **Baby and child development part 6 (1293).**

A telephone marking service offers independent verification of results – details on the monthly MCQ papers. People wanting to register for Pharmacy Update can contact Mary Prebble on 01732 377269.

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GENUS PHARMACEUTICALS

Fish oils do protect the heart – somehow

Fish oils and fatty acids are useful for protection against coronary heart disease but the optimal levels are unclear, say researchers in Scotland.

The action mechanism of omega-3 fatty acids is still undetermined and most studies have shown that fish consumption and coronary heart disease risk have an inverse association.

One study found that individuals who received fish oil capsules had a 15 per cent reduction in risk of fatal and non-fatal cardiac events. However, a Norwegian trial found that fish oil supplements provided no significant benefit to patients after MI, but this was attributed to a high habitual fish consumption in the trial population.

The authors suggested that some of the possible action mechanisms for omega-3 fatty acids' cardioprotective properties include: anti-arrythmic; antithrombotic; anti-atherosclerotic; lowers blood pressure; lowers triglyceride concentrations; and improves endothelial function.

Oily fish, such as mackerel, are a good source of omega-3 fatty acids

Polluted fish may cause some adverse effects, warn the authors, but they add this can be minimised by eating a variety of fish.

The authors suggest that more trials need to be done with fish oils to determine their benefits, but further investigation into their action mechanism is also required to refine the clinical usage and identify new therapeutic targets.

For more information:

www.omega-3info.com

BMJ 2004; 328: 330-5.

Scriptlines

Rotacaps out of stock

Becotide Rotacaps and Ventolin Rotacaps stocks are exhausted in both AAH and UniChem's warehouses.

PSNC has advised pharmacists to return prescriptions with the brand name specified to the prescriber so an alternative product can be given.

For generic prescriptions, PSNC has advised pharmacists that APS manufactures beclomethasone diproprionate dry powder capsules and salbutamol dry powder capsules for inhalation with the brand name Cyclocaps. However, they are not compatible with the GSK Rotahaler and need the APS Cyclohaler.

The *Drug Tariff Part VIII* will be updated from February 1 to recognise the discontinuation of rotacaps.

For more information:

National Prescription Research Centre

Tel: 020 8441 8427.

Postcode prescribing persists for dementia drugs

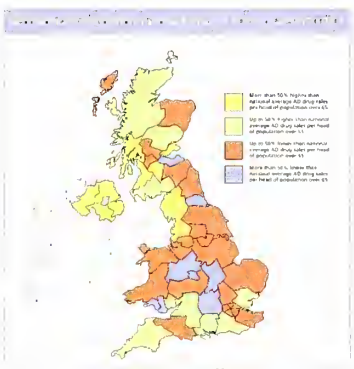
Postcode prescribing of anti-dementia drugs persists, with some areas spending four times more than others, claims a study by Pfizer.

Areas such as Northern Ireland spend as much as £10 per person on dementia drugs on the over 65s, but at the other extreme Lothian, Scotland, spends less than £2 per person.

The strategic health authorities found to be spending the least on anti-dementia drugs were: Thames Valley; Birmingham and The Black Country; Shropshire and Staffordshire; Leicestershire; Northamptonshire and Rutland; Co Durham and Tees Valley; Lothian; Bro Taf and Icheyd Morgannwg, Wales.

Those spending the most on anti-dementia drugs included: the four Nothern Ireland health and social services boards; Lanarkshire; Argyll and Clyde; Ayrshire and Arran; Fife; Cumbria; and Lancashire.

The study's aim was to discover how the NICE guidelines published in 2001 had affected spending patterns for three drugs: donepezil, rivastigmine and galantamine.



Dr Roger Bullock, from the Kingshill Memory Research Centre, Swindon, said: "In many areas proper negotiations with PCTs have not occurred - so budgets are ill defined. Services need to be planned with local PCTs. A failure to do so will only increase the differences shown in this study."

The researchers found that overall spending had increased significantly between 1999 and 2003, however the regional distribution of this spending varied widely. They concluded: "Whilst the variation in per capita spending on Alzheimer's disease drugs between health authorities has fallen, there is still significant geographical variation in the uptake of and access to Alzheimer's disease drugs."

Long-term aspirin use increases pancreatic cancer risk

Long-term use of aspirin in women increases their risk of developing pancreatic cancer, claim researchers in the USA.

A study of over 88,000 women found that those who had taken two or more 325mg aspirin tablets per week were more likely to have developed pancreatic cancer than women who had consumed less than two tablets per week.

The women were questioned biennially for 20 years and those who took aspirin regularly had a 58 per cent increased risk of pancreatic cancer compared with women who never consumed more than two aspirin tablets per week. Women who took 14 or more aspirin tablets per week had an 86 per cent increased risk.

The authors wrote: "Our findings do not support a protective effect of analgesics use on the risk of pancreatic cancer. Rather, aspirin appears to increase the risk of pancreatic cancer after extended periods of use. Risks and benefits associated with the use of aspirin have to be weighed carefully in any recommendations made by healthcare providers."

Around one third of the women studied were classed as current regular users of aspirin, and overall there were 161 new cases of pancreatic cancer, found the study, published in the *Journal of the National Cancer Institute*.

In an accompanying editorial, Dr John Baron from Dartmouth Medical School said: "There are no easy answers to the question of what aspirin and other NSAIDs do to pancreatic carcinogenesis. The findings... are provocative and force us to think carefully about the actions of aspirin and other NSAIDs and the mechanisms underlying pancreatic cancer."

For more information:

J Natl Cancer Inst 2004, 96: 22-8

Pharmacyupdate

Who says learning isn't worthwhile? Update**Knockout** is back for 2004 with double the prize money!

Register now for one of community pharmacy's most popular continuing education courses and you could be in line for a reward of £2,000 or £1,000.

Register for **Pharmacy**update before the end January 2004 and you will automatically be entered for Update**Knockout**2004, and get a £5 discount off the 2004 registration fee of £30.

Update**Knockout** is supported by Genus Pharmaceuticals.

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All Update**Knockout** requires is that you complete the monthly update question papers. If you get the questions wrong you are knocked out. Get them right up to the eliminator stage in October 2004 and you will be registered free of charge for **Pharmacy**update in 2005. Answer three eliminator papers on 2004 Update modules correctly and the prize could be yours!

Make **Pharmacy**update a regular part of your CPD cycle. It's a simple way to keep your clinical knowledge up to date.
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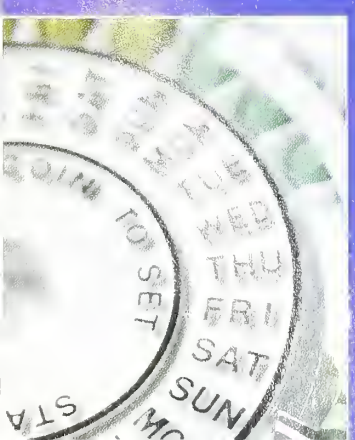
Pharmacyupdate - edited by pharmacists for pharmacists



it's a **Knockout**!

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Put **Pharmacy**update in your CPD portfolio – register now for 2004

Pharmacyupdate appears in Chemist & Druggist every week and will deliver over 30 hours of CPP-accredited learning material in 2004.

Read the modules and test your learning using the monthly question papers. Use C&D's telephone marking service to register your answers and check your results.

If you miss a module, all accredited features appear on C&D;s website at *www.dotpharmacy.com,* along with the question papers.

Pharmacists practising in Northern Ireland will have their registration fee paid by the Northern Ireland Centre for Pharmacy Postgraduate Education & Training (tick box on registration form when applying).

Registering for **Pharmacy**update couldn't be simpler. Complete the coupon below and post it with your cheque to

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Send this completed form to: Mary Prebble, Pharmacy Projects, CMP Information, Sovereign House, Sovereign Way, Tonbridge, Kent TN9 1RW.

☐ Tick this box if you are registering before January 31, 2004, but DO NOT want to be entered into Update**Knockout** 2004.

Poetry in motion from Seven Seas

Seven Seas has joined forces with the English National Ballet and the Arthritis Research Campaign to alert consumers to the dangers posed by bad shoe choice and overexertion which is fuelling an osteoarthritis epidemic among UK women.

Nine out of 10 women regularly wear shoes smaller than their feet, according to research. The result is that by the age of 60, some 70 per cent of women will have osteoarthritis, which can lead to deformities and pain in their feet.

A new 'First First' marketing campaign highlights the importance of long-term footcare.

The initiative is designed to educate consumers about the ways in which they can help prevent joint problems before they occur. One of the suggestions is to take cod liver oil as a preventative measure against developing arthritis.

For more information:
Seven Seas Health Care Ltd
Tel: 01482 375234.

Full Marks is back on TV

Full Marks head lice treatment is back on TV screens this month in a £750,000 national campaign on all terrestrial channels and satellite for three weeks.

The TV commercial is designed to highlight the quick and easy application of Full Marks Mousse.

Full Marks has a 40 per cent share of the head lice market in pharmacy (*Independent Audit MAT share, all chemists, Oct 5, 2003*).

For more information:
SSL International
Tel: 0161 654 3000.

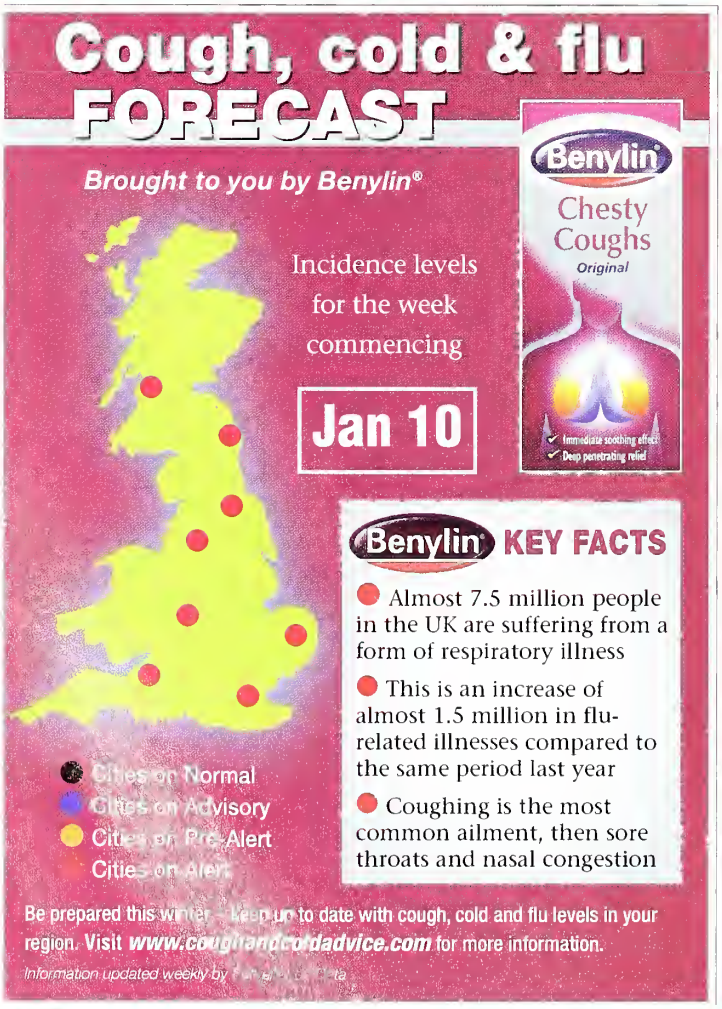
Inbrief

Quiet Life is making a noise

Natural sedative Quiet Life is being advertised on PharmaSite sites in independent pharmacy shop windows for the first time this year.

The campaign will run until the end of January, followed by another burst for four weeks starting on March 29.

For more information:
G R Lane Health Products Ltd
Tel: 01452 507458.



TV next week

Anadin: All areas
Askit Powders: STV, C4, C5, GMTV
Bassett's Soft & Chewy Vitamins: GMTV, Sat
Benylin: All areas except U
Breathe Right: GMTV
Centrum Performance: G, Y, C, A, M, LWT, CAR, C4, C5, Sat
Covonia: B, G, Y, TT, C5, GMTV, Sat
Full Marks Mousse: All areas
Gaviscon Advance: U, C, HTV, W, LWT, CAR, TT, C4, C5, Sat
Imodium Instants: All areas
Just for Men: All areas
Kalms: C5, GMTV, Sat
Lemsip Cold & Flu Direct Lemon & Blackcurrant: All areas except GTV, B, A, CTV, W, M, TT
Lemsip Max Sinus capsules: All areas except GTV, B, A, CTV, W, M, TT
Lloydspharmacy diabetes advertising: All areas except GTV, U, STV, B LWT
Meltus: All areas
Nicorette: All areas except GTV, GMTV
Nicotinell: All areas
Nivea Body Night Renewal Crème: All areas
Nivea Deo Silk: All areas
Nivea for Men Revitalising Crème Q10: All areas
Olbas for children: C5, GMTV
Olbas range: C5, GMTV, Sat
Seabond: All areas
Seven Seas Pure Cod Liver Oil: All areas except U, CTV, GMTV
Seven Seas Multibionta: C4, Sat
Sudafed Non-Drowsy: All areas except U, GMTV

PharmaSite for next week: Robitussin Soft Pastilles – window, **Quiet Life –** in-store, **Zovirax –** dispensary

A-Anglia, B-Border, C-Central, C4-Channel 4, C5-Channel 5, CAR-Carlton, CTV-Channel Islands, G-Granada, GMTV-Breakfast Television, GTV-Grampian, HTV-Wales & West, LWT-London Weekend, M-Meridian, Sat-Satellite, STV-Scotland (central), TT-Tyne Tees, U-Ulster, W-Westcountry, Y-Yorkshire

Rimmel is ready to roll

A rollerball applicator is the newest way to apply loose powder eyeshadow from Rimmel.

Metallic Stars Roller Shadow is designed to control the flyaway tendencies of loose powder and achieve a sheer, ultra-fine finish. The powder can be blended with fingertips for the desired effect.

The eyeshadows come in six shimmering shades of silver, gold, bronze, blue, pink and violet. They are fragrance-free, ophthalmologist and dermatologist-tested and suitable for contact lens wearers.

Rimmel's new Vinyl Stars Lip Gloss gives wet-look shine without mess and stickiness. The lip gloss comes with an applicator and is available in five sparkling shades – Shocking Pink, Burnished Copper, Go Bronze, Fuchia and Clear Pink.

Price: Metallic Stars Roller Shadow £4.99, Vinyl Stars Lip Gloss £4.49

Coty (UK) Ltd
Tel: 020 8971 1300.

Plug the sinusitis knowledge gap

Breathe Right nasal strips are appearing in a new national TV campaign which focuses on sinusitis.

On GMTV until the end of the month, the campaign has been launched following research that shows as many as one in three people suffers from rhino-sinusitis.

A recent survey carried out for Breathe Right found that 44 per cent of UK households contain a sinusitis sufferer. The research also found that only 29 per cent of these sufferers currently purchase a remedy.

Ceuta Healthcare has teamed up with independent ENT surgeon Andrew McCombe to produce consumer leaflets, point of sale material and a new website *www.stuffynose.co.uk*

For more information:
Laser Healthcare
Tel: 01202 780558.

New distributor for Ponds

Ceuta Healthcare has taken over the pharmacy distribution of Lever Fabérge brands Ponds, Mentadent, Signal, Shield and Brut.

For more information:
Ceuta Healthcare
Tel: 01202 780558.

Ransom buys Pickles brands

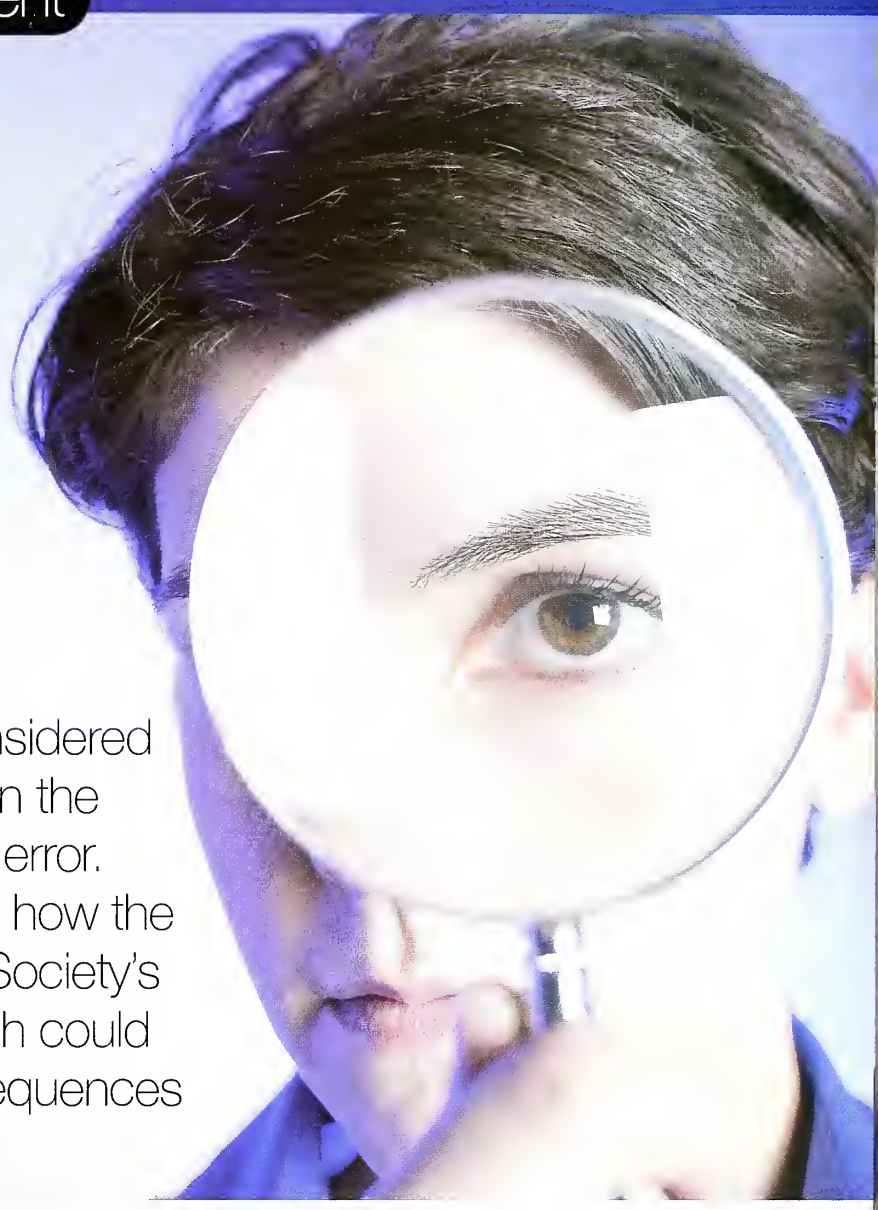
Natural healthcare company William Ransom is acquiring the portfolio of J Pickles.

Manufacture of products which include Snufflebabe and Fiery Jack will continue at Pickles' Knaresborough, N Yorks, site.

Ransom will distribute the brands through Food Brokers.

For more information:
William Ransom & Son plc
Tel: 01462 437615.

Trail and error



The RPSGB's Statutory Committee recently considered the need for audit trails in the context of a dispensing error. David Reissner explains how the case shed light on the Society's approach to errors which could have far-reaching consequences

X Limited owns four pharmacies. A locum manager was the pharmacist in charge of one of the branches, one very busy day just before Christmas 2001. Patients were being asked to call back later, when the superintendent pharmacist, Mr T, arrived. He was carrying stock and laden with boxes of chocolates to be wrapped before he delivered them to local surgeries and residential homes. Some time on that day, a serious dispensing error was made. The Society did not investigate the error until seven months later.

Before interviewing the locum manager and Mr T, the Society's inspector interviewed a counter assistant who said that when Mr T arrived at the premises that day before Christmas, he had done some dispensing. By this time the assistant had been dismissed for gross misconduct in relation to another matter, and had been unsuccessful in bringing an unfair dismissal claim. The locum was interviewed, but was not sure whether Mr T had dispensed or not. The inspector did not interview Mr T until August 2002. Mr T insisted that he had done no dispensing on the day in question. He said he had been too busy carrying stock between branches, getting Christmas presents wrapped and taking them around to the homes and surgeries near each of X Limited's pharmacies. The inspector did not ask Mr T who had made the error.

The allegations

The case was considered by the Society's Infringements Committee, which decided not to take any action against the locum. However, the Infringements Committee decided to make a complaint about X Limited and Mr T to the Statutory Committee. It was not alleged that the dispensing error was, itself, misconduct. Instead, the Infringements Committee said that if a superintendent pharmacist visited a branch and it was very busy, he should have helped out with dispensing. It was implicit in this allegation that the Infringements Committee accepted that Mr T had not dispensed. However, the Society's Council, which approved the decision to refer the case to the Statutory Committee, alleged:

1. Mr T had failed to identify the pharmacist who made the dispensing error.
2. Mr T, as Superintendent of the company, had failed to do enough to prevent the error occurring.

When the Statutory Committee held its inquiry, the Society's Inspector and the dispensing assistant gave evidence. Mr T's evidence was supported by two counter assistants who said he had not dispensed on the day in question. Pharmacists who were working that day at other branches gave evidence of the time when Mr T visited them, showing that he could not have been at the branch where the error occurred at the time the prescription was dispensed.

The defence

Mr T's defence ran along these lines:

1. According to the Code of Ethics, Standard Operating Procedures will not be mandatory until 2005.
2. Everyone makes mistakes. The Council had been unable to point to anything specific that Mr T could have done to avoid the dispensing error he said the locum had made.
3. It was absurd to say that a superintendent was guilty of misconduct if he failed to help with dispensing when visiting a busy pharmacy. After all, there was a pharmacist in personal control. The dispensary might not be big enough for two pharmacists, or a superintendent might not even have recent dispensing experience.
4. Mr T had not failed to identify the pharmacist responsible for the error. The Society's inspector had never even asked him who had made the error, so he could not have been guilty of a failure. Anyway, Mr T had always insisted he had not dispensed, so he had identified the locum by implication.
5. Even if Mr T had dispensed on the day in question, the Code of Ethics requires owners and superintendents to have a retrievable

record enabling them to identify the pharmacist responsible for each professional service. In this case, the pharmacist responsible was the locum who was in personal control of the pharmacy. The Code does not say the owner or superintendent must be able to identify the pharmacist who dispenses each individual prescription.

The decision

The Statutory Committee had no difficulty rejecting the allegation that the superintendent should have done more to minimise the risk of error. The Committee also dismissed the complaint that a superintendent visiting a busy pharmacy would be guilty of misconduct if he did not help out with dispensing. The outcome of the case hinged on whether Mr T had, in fact, done any dispensing because, if he had, he would have been unable to say whether he or the locum had made the dispensing error.

If Mr T had been unable to identify the pharmacist who made the error, did this infringe the requirement in the Code of Ethics to identify the pharmacist responsible for the professional service? In a potentially far-reaching ruling the Statutory Committee said: "In our view it is a responsibility of a superintendent pharmacist to have in place systems or to make arrangements ensuring that a pharmacist responsible for an error can be identified. It must be in the public interest for both disciplinary and safety reasons for the pharmacist in error to be identified.

"The RPSGB representing the public interest must be in a position to know who has made the error to allow investigation of the error to discover, for example, whether it was an isolated and uncharacteristic incident or whether it exemplified a dangerous and wholly unacceptable approach to dispensing."

In fact, having decided that owners and superintendent pharmacists have a duty to identify which pharmacist has dispensed or checked each prescription, the Statutory Committee accepted Mr T's evidence that he had not dispensed on the day in question. It followed that he had correctly identified the locum as the pharmacist who made the error. What was left of the Council's complaint was therefore dismissed.

The significance of the decision

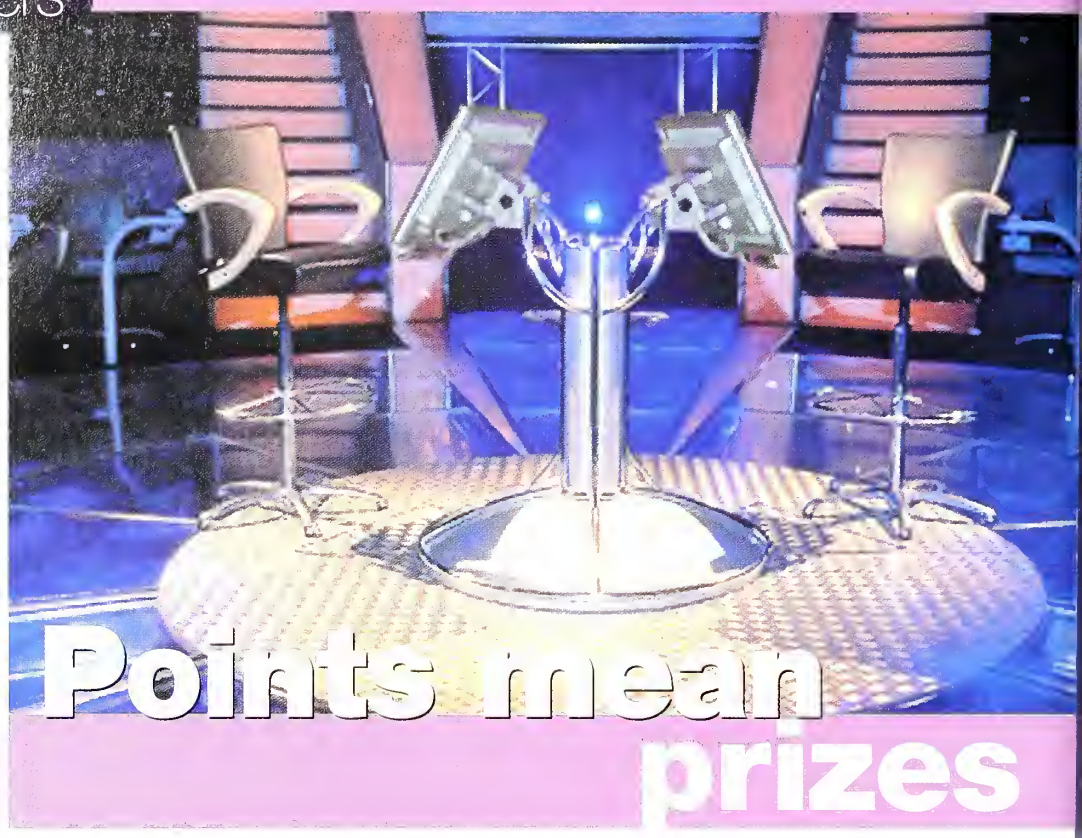
The Statutory Committee has, in effect, rewritten the Code of Ethics, spelling out that a duty to have a retrievable record identifying the pharmacist responsible for a professional service includes being able to say which pharmacist dispensed or checked each prescription. This duty will be particularly important at pharmacies where more than one pharmacist works.

However, despite the importance of being able to establish whether an error is an isolated one or if a particular pharmacist is dangerously prone to error, the Statutory Committee gave little assistance to the profession in suggesting how pharmacists can be identified.

It was suggested during the case that pharmacists should be required to identify themselves by using the "dispensed by" or "checked by" boxes on dispensing labels. While this is common practice, it is not yet a universal one. In any event, the boxes are small, and initials are not always distinctive. One suggestion from the Statutory Committee was that individual pharmacists could be allocated a personal number to write in a box, but this is hardly a generally accepted practice. Moreover, if a patient who has suffered from a dispensing error does not keep the box in which medication has been dispensed, the record made by the pharmacist will not be a retrievable one.

From now on, any owner or superintendent of a company owning a pharmacy where more than one pharmacist works may be guilty of misconduct if an error is made and the pharmacist responsible cannot be identified. The Statutory Committee may be far ahead of the Society's Council in spelling out modern standards of conduct, but perhaps too far ahead. What the profession needs now is clear guidance from its Council as to how it is expected to comply with the vague words in the Code of Ethics and the more specific ruling of the Statutory Committee.

David Reissner is a partner in the Charles Russell law firm and specialises in pharmacy law



Points mean prizes

The new GMS contract awards points (and pounds) for specific indicators. Georgina Craig of the NPA explores the implications for community pharmacy

The General Medical Services contract heralds a new era in primary care. Like the proposed pharmacy contract, its focus is on quality of care, rather than merely volume of work. The contract has significant new funding attached to it – with the bulk of the one third increase in primary care funding planned over the next three years flowing in through general medical services (GMS).

By 2007, £1.3 billion of the total £1.9bn funding increase will be recurrently invested in primary care through the GMS quality and outcomes framework. Improving quality of care, in line with this framework, is how GPs will achieve the "significant increases in income" promised by their negotiators – although clearly practices will need to invest resources to improve quality – so GPs will need to speculate to accumulate.

What does the new GMS contract look like?

The most significant part of the GMS contract (*see figure 1*) for community pharmacy is the quality and outcomes framework, which awards points (and pounds) for achieving clinical, organisational and patient experience quality indicators such as:

- maintenance of a disease register;
- improved levels of measurement and intervention in patients with specified medical conditions; and
- improved control of medical conditions.

The framework is outlined in detail in the new contract[1] – and a good understanding of it is essential for all those working in community pharmacy. During the first three years of the new contract, practices will be able to apply for quality payments to help them to prepare to improve quality. This will fund dedicated time and resources to facilitate change. The system will work as follows.

At the beginning of the year, the practice will set itself a goal of the level of care it hopes to achieve by the end of the coming 12 months. On the assumption that the practice will reach its target, a proportion of the total payment will be paid to the practice in monthly instalments. This will allow the practice to invest over the year in the staff and other resources needed to meet its quality target. These monthly payments are known as "aspiration payments".

The balance will remain unpaid until the end of the year. Once evidence is presented that the level of quality aspired to has been reached, the balance will be paid. This is known as the "achievement payment". If there is a shortfall against the target set, a lesser amount will be paid at year end. If the practice achieves a higher level of quality than it hoped, then an amount greater than the target balance will be paid.

This sounds complicated, but will be easy to calculate in practice since every indicator on the quality framework has points attached to it. A practice can achieve a maximum of 1,050 points – and each point is worth £75 in 2004, rising to £120 in 2005. Points will be recorded on a 'quality score card'. So, by April 2005, an average practice could aspire to earn as much as £126,000 from fully implementing the quality framework alone. Other income will still be paid on a revised, weighted per capita basis. *Figure 2* summarises the medicines management section of the quality framework for general practice. This illustrates the kind of quality indicators practices will need to meet.

Implications for pharmacy

General practice: the new primary care commissioner? Given that a significant amount of the extra funding flowing into primary care will sit within the GMS contract, it follows that the shift in responsibility for service provision is moving away from the PCT to the GP practice. As GPs will be the ones who have easiest access to the new monies, they will decide how care is delivered. Community pharmacists can help GPs to improve quality – and indeed, the new GMS contract recognises this. It states: "Global sum payment arrangements will enable practices to develop greater skill mix with more registered nurses, pharmacists (subject to conflict of interest) ... to work at all levels as part of a practice team." This is promising, but the reference to conflict of interest suggests that there remain concerns at national level about GPs working closely with the pharmacists who dispense for their patients – even though close working with precisely those pharmacists would reap the greatest rewards for patients. But assuming this can be addressed, it is likely that in the future, community pharmacists will find themselves subcontracting work from the GP practice, eg medication reviews of older people, monitoring of people with diabetes etc, instead of from the PCT.

Enhanced services: pharmacy as provider? A number of the services that are envisaged as enhanced services under GMS could be provided by pharmacists, eg anticoagulant monitoring. Although part of

Continued on page 30 ▶

Info resources

The NPA resource pack *A quick reference guide to the quality indicators in the new GMS contract* describes the key GMS quality indicators, what services community pharmacy can offer to support GP practices, examples of the published evidence base and practical resources available to help with service development. The guide can be requested from the NHS Service Development Department by emailing *nhs.dev@npa.co.uk* or telephoning 01727 858687 ext. 3217. Alternatively this resource is available at *www.npanet.co.uk*

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the GMS funding for enhanced services is ring fenced, PCTs will be looking to a variety of providers from whom to commission these services – not just GPs. Recent guidance on the implementation of the GMS contract[1] highlights that PCTs commissioning enhanced services that involve a wide range of constituents must ensure that decision-making processes are inclusive, transparent and fair – so community pharmacists interested in these services should ask to be kept informed of developments.

Public health and patient education: a role for pharmacy? Although the GMS contract includes reference to GPs' role as providers of "holistic care", there is little mention of the practices' role in issues like smoking cessation, sexual health and risk reduction among drug users. This is an opportunity for pharmacy. The National Service Frameworks - notably for diabetes – focus heavily on patient education, yet there is no explicit provision within the GMS contract for this kind of service – again, an opportunity for community pharmacy.

Access is key: there will be big bonuses for practices which meet access targets of a GP appointment within 48 hours - and access to a health professional within 24 hours. Pharmacy-led minor ailments schemes can help practices to meet these targets by freeing up GP time for other work and are likely to be supported by GPs and thus prove popular.

Primary care estate: the new contract will make it easier for GPs to move into new premises, for example where they are experiencing negative equity as a result of a fall in local property values. This is likely to encourage GPs to move into new purpose built centres, like those planned in LIFT developments.[5] Pharmacists need to keep abreast of local primary care estate development plans, detailed in the PCT's strategic service development plan (SSDP).

Out-of-hours: following the implementation of this contract, GP practices will no longer need to provide care during the out-of-hours (OOH) period, defined as 18.30 to 08.00 on weekdays, weekends, bank and public holidays. PCTs will assume responsibility for patient care during this time. The way the contract is designed, most practices will opt out, leaving the PCT to design completely new systems for OOH care. This could include setting up more walk-in centres, making better use of paramedics and hospital facilities, or community pharmacies – some of which are open extended hours already. Pharmacy should engage with PCTs in discussions about how to redesign OOH services immediately.

Conclusion

The new GMS contract heralds a major change in the way primary care is delivered. In the near future, community pharmacy owners could be contracting with their local practice for services to improve quality of care, especially for those with chronic diseases. A prerequisite to this will be a good working relationship with the local practice. If you have not established communication yet, the GMS contract provides a hook for you to start talking. Doing so could be the most important thing you do this year to secure the future of your business.

This article appeared in the autumn edition of the NPA's Pharmacy Practice Matters (Vol 9 no 3).

References available on request.

Figure 1: Key features of the new categories of GMS services

Category	Key features
Essential Services	Every practice will provide essential services. These include the care of patients with conditions from which they are expected to recover (including new symptoms) and the general care of the terminally ill. The GPC will negotiate services and rates nationally. Practices will be paid on a capitation basis, using a formula that reflects patient need as well as list size. Payment will be made directly to the practice by the primary care organisation (PCO), and financed through non-discretionary payment within PCO budgets[A].
Additional Services	It is assumed that all practices will provide additional services, but practices can "opt out" if circumstances dictate. In such circumstances, the practice must give the PCO three months' notice. The PCO has up to nine months to find an alternative provider. Examples of additional services include: vaccination/ immunisation, contraception, child health surveillance, cervical cytology and chronic disease management services. Practices opting out of these services will forego funding. The GPC will negotiate national services and rates, and practices will be paid on a capitation basis, using a formula that reflects patient need as well as list size. Payment will be made directly to practices by the PCO. Additional services will be financed through non-discretionary payments within PCO budgets[A].
Enhanced Services National	National enhanced services will not be provided by all practices, but they will be provided in every locality. Practices can "opt in". Examples include: services provided by GPs with special interests, specialised minor surgery, services for violent patients and out of hours services (after a transitional period). There are two types of national enhanced services. Directed enhanced services must use the nationally agreed service specification and price, which are outlined in supporting documentation to the GMS contract. Examples include extended minor surgery, 'flu vaccinations, treatment of violent patients, child vaccinations for 2003/04. National enhanced services may use the national specifications provided and national bench mark prices, but PCTs can commission a service, more tailored to local needs if they wish. Examples include anti-coagulent monitoring, near patient testing, more specialized drug and alcohol misuse -or sexual health services. Enhanced national services will be funded from PCOs' unified budgets[A] but with a protected minimum level of funding, which PCOs can increase if they wish.
Enhanced Services Local	Enhanced local services are subject to local discretion. They are services agreed between the practices wishing to offer them and the PCO. Examples include: pilot schemes of innovative services, services to meet specific local need eg care of asylum seekers. These services will be funded from PCOs' unified budgets, and will be locally priced. Practices and PCOs can involve the local medical committee in negotiations but this is not essential.

Figure 2: Summary of medication management quality indicators

Indicator	Level 1	Level 2
Collection of prescriptions	72 hours – excl. bank holidays and weekends (**3 points**)	48 hours – excl. bank holidays and weekends (**6 points**)
Medication review	80 per cent of patients on four or more medicines in last 15 months – excl. OTC and topical medication (**7 points**)	80 per cent of patients on repeat medication in last 15 months excluding OTC and topical medication (**8 points**)
Liaison with pharmaceutical advisor	Meeting held annually; three actions on prescribing agreed (**4 points**)	Meeting held annually; three actions on prescribing agreed; evidence of change in line with agreed actions presented (**4 points**)
Medication record available at all consultations in surgery (**2 points**)		
Equipment and drugs for emergency treatment anaphylaxis kept up to date (**2 points**)		
Systems for checking expiry dates (at least annually) in place (**2 points**)		
Where practice injects neuroleptics, system in place to identify non attenders (**4 points**)		

Adapted from The GMS contract: investing in general practice[4]

1. PCTs are awarded a unified budget based on a national formula, by the DoH to cover all the services they are responsible for providing and commissioning. By 2004, PCTs will hold around 75% of total NHS spending. Some parts of these budgets are "ring fenced" and can only be used to fund specified services. These monies are called "non discretionary payments" because the PCT has no discretion in relation to their use. All other funding within the unified budget can be used as the PCT sees fit.

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Double act

Gordon's Chemist in Bangor, Co Down, will be without two key members of staff for one weekend in February. Pharmacy Travel, the travel agency for everyone in the business, is to blame.

Pre-registration graduate Fiona Whyte was the winner of October's prize of a three-day break for two in a Historic Country House Hotel.

"Sorry it has taken so long to let you know, but since I am taking the manager of my shop, Sianine Hanna, it has taken some time for us to organise when we would both be able to go!" she says.

Fiona and Sianine will be gone for three days to Thoresby Hall Hotel in Nottinghamshire.

For details of this month's Pharmacy Travel family offers and prize draw see opposite this week or look in this month's *Community Pharmacy* magazine.

Fiona Whyte (right) and manager Sianine Hanna – off to Robin Hood country in February

Atkins beached

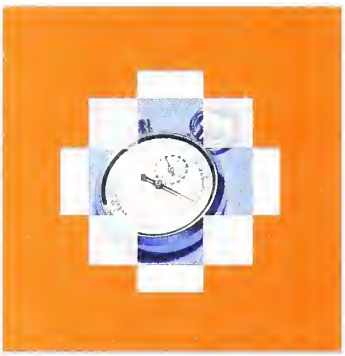
Anyone looking to shift some excess Christmas weight but concerned about the possible side-effects of the Atkins diet may be interested to hear about the South Beach Diet.

Apparently it is all the rage in the USA with many celebrity fans, including Oprah Winfrey and Bill Clinton.

South Beach differs to Atkins by balancing moderate amounts of proteins and fats with a carbohydrate routine based on the foodstuff's glycaemic index (GI). GI grades food on the rate it raises blood sugar levels, so high GI foods like white bread and bananas are considered "bad", whereas low GI foods such as oily fish, apples and milk are considered "good".

The first phase of the diet lasts two weeks and cuts out all carbohydrates, alcohol, fruit and dairy. The second and third phases reintroduce these foods until a common sense eating plan is established.

Cynics may be interested to know that the diet's creator, Dr Agatston, is a cardiologist, who formulated the diet to prevent heart disease and then noticed that patients lost weight. His hometown of Miami influenced the name and a craze was born.



Swiss doctors watch clocks

British GPs who complain that patients waste their time may be eager to see how a new Swiss system works out. There, doctors have started charging patients for every five minutes they spend with them. This includes the time taken to say hello and goodbye and make notes after the patient has left.

The new legislation came into effect on January 1 and aims to contain health costs. Most patients will not be affected by the new system as all medical bills are footed by their compulsory private health insurance.

However, the medical profession is less than happy with the new system, saying that the amount of detail contained in the rules adds pressure to its already stressful lives.

Belgian antibubbly

A Belgian researcher may have upset advertising heads in the beer industry by likening the drink to dishwater. His comment followed the successful creation of antibubbles, the opposite of bubbles, in beer (below).

An antibubble is a thin film of air inside a liquid enclosing a pocket of the same liquid. This differs from a bubble which is a thin film of liquid in air enclosing a pocket of air. The different structure of an antibubble means that it moves down in liquid, instead of up.

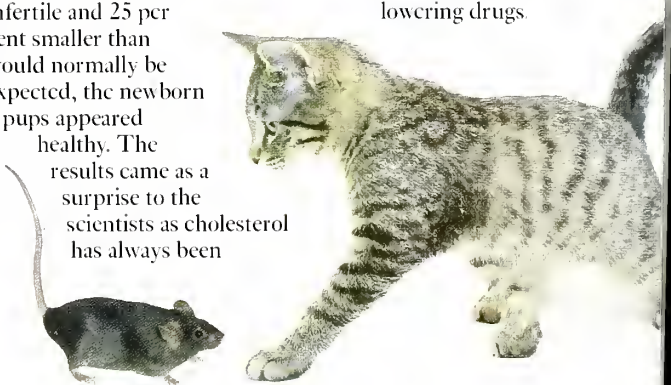
The phenomenon of antibubbles cannot be created in pure water, alcohol or oil. However, beer contains a protein which acts as a surfactant, and this led to the unfortunate comparison drawn by the lead researcher. All of which is bound to please British real ale fans who have always maintained that continental beers are only good for one thing.

Low-fat cat snacks

Snacks that are healthy and fun to catch for cats may be available soon, as US scientists have created cholesterol-free mice using genetic modification.

The research team altered a gene that encodes a cholesterol-making enzyme. Apart from being infertile and 25 per cent smaller than would normally be expected, the newborn pups appeared healthy. The results came as a surprise to the scientists as cholesterol has always been thought essential for survival.

Humans with a similar genetic mutation are extremely rare and the two known cases both died as result of multiple organ failure. Despite this, the scientists are optimistic the discovery may help to develop new cholesterol-lowering drugs.



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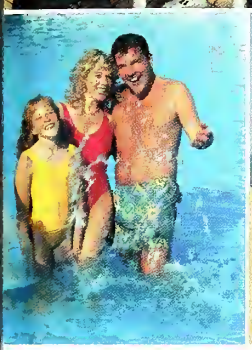

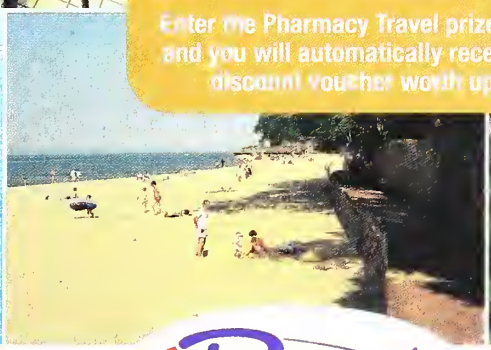

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The prize is for 2 adults and 2 children under 18 and can be taken any time between 23 April and 8 October 2004 (subject to availability). It includes 3 nights in an Ambassador room at Harcourt Sands with half board meals, all leisure activities/ entertainment and complimentary wine and fruit on arrival.

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